THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

\- - -

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL NO. 2804
THIS DOCUMENT RELATES TO ALL CASES:	:	CASE NO. 1:17-MD-2804 Hon. Dan A. Polster

\- - -

Friday, April 26, 2019

\- - -

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

\- - -

Videotaped deposition of DAVID A. KESSLER, M.D. (Day 2), taken pursuant to notice, was held at Baron & Budd, 600 New Hampshire Avenue NW, Floor G, Washington, DC 20037, beginning at 8:07 a.m., on the above date, before Lisa V. Feissner, RDR, CRR, Notary Public.

\- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

APPEARANCES:
LEVIN PAPANTONIO THOMAS MITCHELL RAFFERTY & PROCTOR PA
BY: TROY A. RAFFERTY, ESQUIRE
316 South Baylen Street - Suite 600
Pensacola, Florida 32502
(850) 435-7163
trafferty@levinlaw.com
-- Representing Plaintiffs

SEEGER WEISS LLP
BY: PARVIN K. AMINOLROAYA, ESQUIRE
BY: KSENIYA LEZHNEV, ESQUIRE
77 Water Street - 8th Floor
New York, NY 10005
212-584-0700
paminolroaya@seegerweiss.com
klezhnev@seegerweiss.com
-- Representing Plaintiffs

LIEFF CABRASER HEIMANN & BERNSTEIN
BY: LEXI J. HAZAM, ESQUIRE
275 Battery Street - 29th Floor
San Francisco, CA 94111-3339
(415) 956-1000
lhazam@lchb.com
-- Representing Plaintiffs

SPANGENBERG SHIBLEY & LIBER LLP
BY: PETER H. WEINBERGER, ESQUIRE
1001 Lakeside Avenue East - Suite 1700
Cleveland, OH 44114-1149
(216) 600-0114
pweinberger@spanglaw.com
-- Representing Plaintiffs

APPEARANCES: (Continued)
BARON & BUDD P.C.
NOAH RICH, ESQUIRE
(via video stream / realtime stream)
600 New Hampshire Avenue, NW
The Watergate, Suite 10-A
Washington, DC 20037
(202) 333-4562
nrich@baronbudd.com
-- Representing Plaintiffs
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
BY: MATIAS BUSTAMANTE, ESQUIRE
(via video stream / realtime stream)
275 Battery Street - 29th Floor
San Francisco, CA 94111
(415) 956-1000
mbustamante@lchb.com
-- Representing Plaintiffs

DECHERT LLP
BY: HOPE S. FREIWALD, ESQUIRE
Cira Centre
2929 Arch Street
Philadelphia, PA, 19104-2808
(215) 994-2514
hope.freiwald@dechert.com
and
DECHERT LLP
ALEJANDRO HERRERA, ESQUIRE
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036-6797
(212) 698-3500
alejandro.herrera@dechert.com
-- Representing the Purdue Defendants

APPEARANCES: (Continued)
ARNOLD & PORTER KAYE SCHOLER LLP
BY: JOSHUA M. DAVIS, ESQUIRE
601 Massachusetts Avenue, NW
Washington, DC 20001-3743
(202) 942-5743
joshua.davis@arnoldporter.com
-- Representing the Endo and Par Defendants
and
ARNOLD & PORTER KAYE SCHOLER LLP
BY: JOHN CELLA, ESQUIRE
(via video and realtime stream)
601 Massachusetts Avenue, NW
Washington, DC 20001-3743
(202) 942-5743
john.cella@arnoldporter.com
-- Representing the Endo and Par Defendants

KIRKLAND & ELLIS LLP
BY: JENNIFER LEVY, ESQUIRE
1301 Pennsylvania Avenue, NW
Washington, DC 20004
(202) 389-5211
jennifer.levy@kirkland.com
and
KIRKLAND & ELLIS LLP
BY: MICHAEL LeFEVOUR, ESQUIRE
300 North LaSalle
Chicago, IL 60654
(312) 862-3728
michael.lefevour@kirkland.com
-- Representing the Allergan Defendants

MORGAN LEWIS & BOCKIUS LLP
BY: WENDY WEST FEINSTEIN, ESQUIRE
One Oxford Centre
Thirty-Second Floor
Pittsburgh, PA 15219-6401
(410) 560-7455
wendy.feinstein@morganlewis.com
-- Representing the Teva Defendants

APPEARANCES: (Continued)
O'MELVENY & MYERS LLP
BY: AMY LAURENDEAU, ESQUIRE
610 Newport Center Drive
17th Floor
Newport Beach, CA 92660
(949) 823-7926
alaurendeau@omm.com
and
O'MELVENY & MYERS LLP
BY: VINCENT S. WEISBAND, ESQUIRE
Times Square Tower
7 Times Square
New York, NY 10036
(212) 326-2228
vweisband@omm.com
-- Representing the Janssen Defendants

MORGAN LEWIS & BOCKIUS LLP
BY: JOHN P. LAVELLE, JR., ESQUIRE
(via video and realtime stream)
1701 Market Street
Philadelphia, PA 19103-2921
(215) 963-4824
john.lavelle@morganlewis.com
-- Representing the Defendant
Rite-Aid of Maryland, Inc.

REED SMITH LLP
BY: STEVEN J. BORANIAN, ESQUIRE
101 Second Street - Suite 1800
San Francisco, CA 94105
(415) 659-5980
sboranian@reedsmith.com
and
REED SMITH LLP
BY: LUKE PORTER, ESQUIRE
(via teleconference)
101 Second Street - Suite 1800
San Francisco, CA 94105
(415) 659-5980
lsmith@reedsmith.com
-- Representing the Defendant
AmerisourceBergen Drug Corporation

APPEARANCES: (Continued)

JONES DAY
BY: BRANDY H. RANJAN, ESQUIRE
325 John H. McConnell Boulevard
Suite 600
Columbus, OH 43215-2673
(614) 469-3939
branjan@jonesday.com
-- Representing the Defendant Walmart Inc., f/k/a Wal-Mart Stores, Inc.

ROPES & GRAY LLP
BY: RICHARD L. GALLAGHER, ESQUIRE
Three Embarcadero Center
San Francisco, CA 94111-4006
(415) 706-1033
richard.gallagher@ropesgray.com
and
ROPES & GRAY LLP
BY: CHRISTINE D'AURIA, ESQUIRE
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
(617) 235-4741
christine.dauria@ropesgray.com
-- Representing the Defendant Mallinckrodt LLC

WILLIAMS & CONNOLLY LLP
BY: PAUL E. BOEHM, ESQUIRE
725 Twelfth Street, NW
Washington, DC 20005
(202) 434-5366
pboehm@wc.com
-- Representing the Defendant Cardinal Health, Inc.

FOX ROTHSCHILD LLP
BY: ZACHARY MARTIN, ESQUIRE
(via teleconference)
Stone Manor Corporate Center
2700 Kelly Road - Suite 300
Warrington, PA 18976
(215) 918-3680
zmartin@foxrothschild.com
-- Representing the Defendant Prescription Supply, Inc.

APPEARANCES: (Continued)

BARTLIT BECK LLP
BY: SHARON DESH, ESQUIRE
(via teleconference)
54 West Hubbard Street
Suite 300
Chicago, IL 60654
(312) 494.4445
Sharon.Desh@BartlitBeck.com
-- Representing the Defendant Walgreens

ALSO PRESENT:

CHRIS RITONA, Videographer
Golkow Litigation Services
GERARD MAGLASANG, Legal Assistant
SEEGER WEISS LLP

ALSO PRESENT via video stream/realtime stream:

GRETCHEN KEARNEY
EMMA KABOLI
Baron & Budd P.C.

CHARLES BACHMANN
Seeger Weiss LLP

- - -

I N D E X

- - -

- - -

E X H I B I T S

- - -

- - -

E X H I B I T S
(cont'd)

- - -

- - -

E X H I B I T S
(cont'd)

- - -

- - -

E X H I B I T S
(cont'd)

- - -

- - -

DEPOSITION SUPPORT INDEX

- - -

Direction to Witness Not to Answer

Request for Production of Documents

Stipulations

Question Marked

- - -

(It is hereby stipulated and agreed by and among counsel that sealing, filing and certification are waived; and that all objections, except as to the form of the question, will be reserved until the time of trial.)

- - -

VIDEO OPERATOR: Today's April 26th. The time is 8:07 a.m., and we are now on the record.

This is the continuation of the deposition of David A. Kessler, M.D., and he has been previously sworn in.

You may proceed.

MR. DAVIS: Thank you.

DAVID A. KESSLER, M.D., having been previously duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. DAVIS:

Q. Good morning, Dr. Kessler.

A. Good morning, sir.

Q. My name is Josh Davis. I represent

Page 433

Endo and a number of Endo affiliates, including Par Pharmaceuticals.

I'm going to ask you some questions generally and a fair number of questions about Endo specifically.

Okay?

A. Thank you, sir.

Q. You recall yesterday testifying that you're not a mind reader?

A. Yes.

Q. Do you recall testifying yesterday that you're not going to offer opinions about the intent of authors of particular documents, correct?

A. Not about intent.

Q. Okay. And is it fair to say that your report with respect to Endo refers to a number of internal Endo documents?

A. Yes.

Q. And it quotes from those documents; is that right?

A. In part, yes.

Q. And that includes internal Endo e-mails?

Page 434

A. Yes.

Q. And internal Endo marketing strategy documents?

A. Correct.

Q. And so you're not going to offer an opinion about the intent of the authors of those documents; is that right?

A. No. Just anything that's objective evidence, I will base my opinions on.

Q. Dr. Kessler, while you were at the FDA, did you communicate in writing with other FDA employees?

A. I'm sure.

Q. Did you communicate through internal FDA memoranda?

A. Can I just give a caveat to that? Most of my interactions, just the technology at the time, was probably verbal is my recollection. I did not do e-mail. It was not my style to write memos or -- I'm not saying there's not things in my handwriting, but there's certainly orders, there's regulations. The things that I wrote tend to be formal documents.

Page 435

Q. Certainly you received memoranda for those who reported to you, correct?

A. Of course. You asked me what I wrote. My style was not to write a lot except official documents.

Q. You received communications during your time at FDA, correct?

A. Of course, sir.

Q. And those included written communications?

A. Of course, sir.

Q. And did that include e-mail, after e-mail was available to you at the FDA?

A. You know, you're pushing my memory.

Q. Fair.

A. It was '97 when I left. I think there may be a little, but it's nothing like it was today, sir.

Q. Did you receive internal FDA presentations during your time at FDA?

A. Many of those. Not only -- I had presentations -- as they say in Washington, briefings about briefings.

Q. Fair. Is it -- and you'd agree

Page 436

that not every internal FDA memoranda that you -- memorandum that you received reflects the final position of FDA, correct?

MR. RAFFERTY: Object to the form.

A. The memorandum reflects what it reflects.

Q. And you would agree that not every memorandum you received at FDA reflects the final position of FDA on the issue described in the memorandum, correct?

MR. RAFFERTY: Object to the form.

A. If you can clarify what you mean by "final position."

Q. Does FDA take final positions on issues?

A. FDA -- there's a legal component to that, right, of what is a final agency action. That's why I'm trying to just be careful. That's a legal term because of -- you know, there's a complexity to final agency action and what that means.

Q. A single memorandum to you would not reflect FDA's position on an issue, correct?

Page 437

A. Depends on the memorandum. It could or it could not.
Q. Well, it would be improper to assume that a single memorandum to you necessarily reflects FDA's final position, correct?
A. If it were a memorandum from the President of the United States, it probably may be the final agency action. It depends on the memo, sir.
Q. I agree with that.
Let's say it's a memorandum from someone several, several layers below you at FDA informing you about a particular issue. It would be improper to assume that a memorandum of that type reflects FDA's final position on that issue, correct?
A. Not necessarily.
MR. RAFFERTY: Object to the form.
A. It depends. Happy to explain.
Q. Does every memorandum you received at FDA reflect the final position of FDA?
A. Not necessarily, no.
Q. That's a no, right?

Page 438

A. Not necessarily.
Q. Dr. Kessler, when FDA approves -- you're familiar with what a New Drug Application is?
A. Yes.
Q. And does FDA from time to time approve New Drug Applications?
A. Correct.
Q. And when FDA approves a New Drug Application, that's based on review of that New Drug Application, correct?
A. Correct.
Q. And it's based on review of everything in that New Drug Application, correct?
A. I wouldn't agree with that statement.
Q. FDA -- is it your testimony that FDA approved New Drug Applications without reviewing the complete New Drug Application?
A. FDA does not necessarily review every page out of millions and millions of pages. That would be folly if you thought FDA had those resources. I'm happy to explain.

Page 439

Q. There's information -- I just want to make sure your testimony is clear. It's your position that there's information contained in New Drug Applications that FDA ignores?
A. I didn't say that.
MR. RAFFERTY: Object to the form.
Q. Well, you certainly said there's information contained in New Drug Applications that FDA doesn't review, right?
A. That's what -- exactly what I said. I didn't say they ignore it.
Q. What's the difference between not reviewing and ignoring?
A. One is -- one is a -- they're different words, sir. I mean, they imply different things. And I'm happy to explain that, if you'd like. Reviewing -- a reviewer -- let me step back so I can put this -- answer your question more broadly.
As you know, when I went to hearings, they would make fun of FDA sometimes, a member of Congress, by just bringing in a New Drug Application to show how vast it is. It

Page 440

would fill this room.
The information is available, and when I was there it became electronic, right, so you can search it, right. You have it available.
It's not that you -- there's limited resources. So FDA can review things. Doesn't -- does not -- ignore, to your point, has a deliberate component, right. FDA reviews to the best of its resources and its ability and what it thinks is salient. Doesn't deliberately ignore. But no one -- no one thinks that every page is reviewed.
Q. Are submissions to FDA of promotional pieces for review as voluminous as New Drug Applications?
A. I don't think so. I mean, depending on the size of the NDA. There are short NDAs, and again, what you mean by an NDA. There's a whole range of NDAs. In general, I would not think so.
Q. And when FDA reviews a promotional piece, it reviews the entire submission, correct?

Page 441

A. I wish.
MR. RAFFERTY: Object to the form.
Q. So again, your position is, when FDA receives a submission of a promotional piece -- launch promotional pieces to review, it doesn't review the entire submission?
A. It depends on the resources the agency has available, and again, what the reviewer thinks is salient.
Q. If FDA had sufficient resources, you would agree that the best course of action would be for FDA to review the entire submission, correct?
A. No. I would -- would you like me to explain?
Q. The best course -- if resources were not an issue, you don't believe that the best course of action would be for FDA to review the complete submission of a promotional piece?
MR. RAFFERTY: Object to the form.
A. The agency has to focus -- even if it had endless resources, right, the agency has to focus on the public -- what's important for

Page 442

the public health and what's important for safety. Even if you had umpteen resources, right, you focus on what's -- what you think is important, right. I think that's --
Q. Again, I'm taking resources out of the equation, okay? FDA has infinite resources. There's no need to focus. FDA can look at everything.
The best course in that situation would be for FDA to review the complete submission, correct?
MR. RAFFERTY: Object to the form.
A. There aren't enough people -- I mean, there are not enough people, right. Even if you had unlimited dollars, there's not enough talent, right, to be able to focus on everything, just -- I'm having -- trying to comprehend the universe that you're living in or you're trying to -- making a hypothetical. I apologize. I just don't understand that.
Q. I'm trying to identify what you believe to be the best-case scenario with respect to -- let's go back to NDAs for a second. I'm trying to identify the best-case

Page 443

scenario in your mind for review of a New Drug Application.
You would agree that the best-case scenario, putting resources aside, would be for FDA to review the entire New Drug Application before it approves that NDA, correct?
A. I would not make that -- I would not testify to -- in those words in front of Congress. I don't think that would be -- if there's 50 million pages, I don't believe it would -- putting an eyeball against every line of those 50 million pages would be the best scenario. I think that would be folly to be the basis to review 50 million pages.
Q. Let me make sure this is clear.
As the former FDA Commissioner, your position is that the best-case scenario for FDA would not be to review a complete New Drug Application prior to its approval?
A. That's --
MR. RAFFERTY: Object to the form.
A. That's not what I testified. That's not what I said previously. I'm happy to explain.

Page 444

Q. Well, if you didn't say that your position is that the best-case scenario for FDA would not be to review a complete New Drug Application prior to its approval, that means that the best-case scenario for FDA would be to review a complete New Drug Application prior to its approval.
MR. RAFFERTY: Object to the form.
Q. It either is or isn't the best-case scenario.
MR. RAFFERTY: Object to the form.
A. It's certainly -- if you want to make a general statement that -- about complete -- reviewing a complete, sure, but that should not be interpreted as an eyeball against every single line. Just means what you mean by review of complete, sir.
Q. Are you familiar with Percocet, Dr. Kessler?
A. I am.
Q. And Percocet was an approved medication and was on the market when you were the Commissioner at the FDA; is that correct?
A. That is correct.

Page 445

Q. And you didn't have any direct personal involvement with Percocet when you were the Commissioner at FDA, correct?
A. Not to my knowledge, sir.
Q. With respect to Endo, Dr. Kessler, the opinions you're offering in this litigation are limited to two Endo medications, Percocet and Opana ER, correct?
A. I think that's correct. I'm just trying to make sure there's nothing on the generic side. But -- so I just have to put an asterisk to double-check that. But I think you're correct.
Q. What would you need to do to double-check that?
A. I just want to review the report, because there's -- obviously there's the issue of branded generics, and I just would want to review my report.
But I think, in essence, you're correct. That's certainly what I'm focused on.
Q. If you could at the break confirm that you're correct that the only two Endo products for which you offer an opinion are

Page 446

Percocet and Opana ER, I'd appreciate that.
A. Happy to do that, sir.
Q. You're not offering any opinions with respect to Par Pharmaceutical, are you, Dr. Kessler?
A. So the record can be -- correct. I'm focused on the history -- on drugs. There's a lot of manufacturers. So only to the extent if there's a drug, Percocet or Opana, so -- corporate histories sometimes get complicated, and I may not be fully cognizant of all corporate history, but -- in general.
So we can stay to what drugs I'm issuing an opinion on. I'm happy to do that. Corporations become complicated in this current world.
Q. Are you familiar with Qualitest Pharmaceuticals?
A. Yes.
Q. Are you offering any opinions with respect to Qualitest?
A. There's nothing, I believe, in my report. But if you ask me questions, I'm happy to discuss it.

Page 447

Q. I'd like to talk with you, Dr. Kessler, about your opinions regarding Endo's promotion of Percocet.
A. Yes, sir.
Q. Do you have your Exhibit 1 of your report in front of you?
A. I have my copy, sir.
Q. Your version of your report in front of you?
A. Happy to pull it up.
Q. And just so the record is clear, I think your report has been marked as Exhibit 1 already.
A. I'm sure.
Q. We can work both off our own copies here, which may be more efficient.
A. Thank you.
Q. On page 110 of your report --
A. Can I just get there, please.
Q. Uh-huh.
A. Thank you, sir.
Q. Specifically paragraphs 191 and 192, please.
A. Yes.

Page 448

Q. You offer an opinion regarding Endo's marketing strategy for Percocet, correct?
A. I'm sorry. I didn't hear your question.
Q. You offer an opinion regarding Endo's marketing strategy for Percocet, correct?
A. Not -- in those paragraphs? I'm sorry. I'm confused.
Q. Do you offer an opinion regarding Endo's marketing strategy for Percocet?
A. Yes. I don't think in that paragraph. That's what I'm confused.
Q. In paragraphs 191 and 192, you cite to two Endo business and marketing plans, correct?
A. Yes, sir.
Q. And both of those plans are from the year 2002, correct?
THE WITNESS: Gerard, can you do me a favor and just pull the binder for 191 and 192, please.
Unless you have the documents.

Page 449

Thank you.
A. So the second document is dated April 25th, 2002. And I would need to go back and check the metadata on one unless I cite it here on 346. The document I cite in 346, I just have the native, and I don't have a date. I apologize.
Q. Doctor, you're about to lose your microphone.
A. Thank you, sir.
Q. You don't know whether either of those business plans were final business plans, do you?
A. I only know the words on the documents as they're stated.
Q. Yes or no, you don't know whether those two documents are -- those two business plans are final business plans?
A. The documents don't, on the face of them, state one way or the other.
Q. So you don't know whether those are final business plans, correct?
A. The documents don't state one way or the other.

Page 450

Q. Which means you don't know whether those are final business plans, correct?
A. I only know what the documents state.
Q. And you've said that the documents don't say whether they're final, which means you don't know whether those are final marketing plans?
MR. RAFFERTY: Object to the form, asked and answered.
Q. Correct?
A. I know what the documents state. I can go back and review them in broader context to get that answer, if you'd like.
Q. Well, you just said the documents don't state whether they're final or not, so reviewing them is not going to give you an answer to the question, right? You're not going to know the answer to whether or not those documents are final whether you review them again or not, right?
MR. RAFFERTY: Object to the form.
A. That's certainly knowable by reviewing a database. I review a lot of

Page 451

business plans, and I -- you can see from context. You can see from versions. There are a lot of ways to determine the answer to your question. I'm happy to do more research to get the answer to your question.
Q. You've not done that with respect to those two documents, correct?
A. I have read those documents. That's what I've done with regard to those documents.
Q. But not sufficiently to know right now whether those are final marketing plans or not, correct?
A. I have read those documents to determine -- your question of what's sufficient or not, I'd have to do more research to answer your question.
Q. You don't know the answer to my question is what you're saying, right? You don't know whether those are final documents or not?
A. I only know what those documents say.
MR. RAFFERTY: Object to the form.

Page 452

A. I can't say any more.
Q. This will go a bit more efficiently if you can just give me a straight answer to my question. These are not complicated questions.
So this is the same problem that we ran into yesterday. It's the same problem that I believe we're all going to face. And it's the same problem that's prejudicing both my client and many of the other co-defendants here today. We're wasting time on answers that are not strictly responsive to the questions that we're asking.
I would appreciate it, Dr. Kessler, if you could give me a succinct, responsive answer to my questions going forward. That will make things far more efficient and will lessen the prejudice that my client is experiencing with the time that we have available together and will lessen the prejudice to my co-defendants and my colleagues for the time that they have available. I'd appreciate that.
MR. RAFFERTY: What we're wasting time on is giving speeches that are

Page 453

inappropriate under the protocol and that are, quite frankly, incorrect. He has answered succinctly all of your questions so far this morning. So ask your questions, and he will continue to answer them.

Q. Dr. Kessler, on page -- actually, you know what, sticking with those two business plans, you don't know whether those business plans were ever presented to anyone, do you?

A. I only know what's in these, so obviously right now I'd have to go do more research to see the audience.

Q. See, that's a no. If you answer that --

MR. RAFFERTY: It's not a no, and you're not going to instruct this witness on how to answer a question, Mr. Davis. It's not going to happen. Ask him the questions.

He just said he would have to go get more research. You can take whatever you want. Ask the questions; he'll give you the answer.

Page 454

MR. DAVIS: I'm asking whether he knows it, and when he says, I would have to go do more research, that is a no. That means he doesn't know, Troy.

MR. RAFFERTY: No, the answer is whatever the answer is that he gives, Mr. Davis, so --

MR. DAVIS: I think you've had this conversation off the record with my co-counsel yesterday. You saw what Special Master Cohen said during the Eagleman deposition about our entitlement to yes or no answers to questions that call for yes or no answers. I'm simply asking that Dr. Kessler provide a yes or no answer to yes or no questions.

MR. RAFFERTY: He has given you the answer that you've -- to the questions that you've asked. And I don't know what context was going on with Eagleman, but I can tell you that Dr. Kessler has been answering and been responsive to everybody's questions.

Page 455

MR. DAVIS: Okay. Well, I can tell you if this continues, then we're going to do our best to get Special Master Cohen on the phone to give the same directive that he's given in other contexts.

MR. RAFFERTY: I have no problem with that, and I think a clear reading of this record will show that Dr. Kessler has been more than responsive.

Q. Dr. Kessler, you don't know to whom, if anyone, those presentations were made, right, the two presentations we've been talking cited in paragraphs -- or referred to in paragraphs 191 and 192 of your report?

A. You're correct, those documents don't reflect that.

Q. And so you don't know that then?

A. I know what -- that's correct. I know what's on these documents.

Q. Dr. Kessler, turning to the next page in your report, page 111, you refer to -- or you state that Endo's promotional plans for

Page 456

Percocet, including using medical education to market Percocet, correct?

MR. RAFFERTY: What paragraph are you on?

MR. DAVIS: I'm sorry, paragraph 194 on page 111.

A. That's exactly what that says.

Q. Okay. And in support of that opinion, you cite to a 1998 mid-year update on goals and objectives, correct?

A. Yes, sir.

Q. And just --

A. Hold on one second, please.

Q. Actually, you know, just so we don't have to flip through that, I can mark one for you, sir.

A. Thank you.

(Exhibit Kessler-12 marked for identification and attached to the transcript.)

BY MR. DAVIS:

Q. I'll show you what's been marked as Kessler Exhibit 12. This is the 1998 Mid-Year Update on Goals and Objectives that you refer

Page 457

to in paragraph 194.1, correct?
A. Correct.
Q. It bears the Bates number ENDO-OPIOID_MDL-05967764, correct?
A. Correct.
Q. And this is a mid-year update on goals and objectives for one Endo employee, correct?
A. That's what that says.
Q. That one Endo employee is Linda Kitlinski; is that right?
A. Correct.
Q. Who is Ms. Kitlinski?
A. Just give me one second. I'd have to go back and double-check exactly her title.
Q. As you sit here today, you don't know who Ms. Kitlinski is, right?
A. I -- I'd have to go back and review. I don't -- I don't have it at the top of my head. I don't have it -- let me -- let me just double-check that. Hold on one second.
Q. What are you using to double-check who Ms. Kitlinski is?
A. I just want to check my report for

Page 458

a second, please.
Q. Is Ms. Kitlinski -- was Ms. Kitlinski in 1998 the CEO of Endo?
A. I don't have that in my -- I don't have that in my head right now.
Q. Was Ms. Kitlinski the chairman of the board of directors of Endo at that -- in 1998?
A. I don't believe so, but I -- again, let me see if I can --
Q. Was Ms. Kitlinski the president of Endo in 1998?
A. I don't believe so, but again, I don't -- let me just see if I have -- I have a chart of all titles, and I'm just -- just give me a second, if I can see if I can find it. Just give me one more second, please.
I don't have the -- actually, I have the deposition. I can find it. But I don't --
Q. Do you know whether Ms. Kitlinski was deposed?
A. Yes.
Q. Did you read the entirety of her

Page 459

deposition transcript?
A. No, I did not. I searched -- it was part of my search.
Q. And these are Ms. Kitlinski's mid-year goals and objectives, correct?
A. That's correct.
Q. Okay. And you don't know whether -- certainly Ms. Kitlinski's 1998 mid-year goals and objectives aren't necessarily Endo's goals and objectives, correct?
MR. RAFFERTY: Object to the form.
A. I can't answer that question. I just don't -- I don't know -- I can't answer that question.
Q. You can't tell me that Ms. Kitlinski's 1998 mid-year goals and objectives are the same as Endo's corporate goals and objectives, correct?
MR. RAFFERTY: Object to the form.
A. They could be. They could -- I mean, they could be; they could not be.
Q. You don't know?
A. I only know what this document

Page 460

reflects as far as goals and objectives, and she was an Endo employee.
Q. Okay. And again, you're not offering any -- any opinion as to what Ms. Kitlinski actually meant by any of the words in this document, correct?
A. The words speak for themselves. I'm not -- I'm not going beyond the words, sir.
Q. You don't know whether Ms. Kitlinski's goals and objectives extended beyond this -- the middle of 1998, correct?
MR. RAFFERTY: Object to the form.
A. I only -- that would be fair. There would be mid-year goals. Goals usually reflect a period of time.
Q. And this period of time is the middle of 1998, right?
A. That's fair.
Q. Okay. Dr. Kessler, you're -- you understand that there -- do you understand there's a difference between promotional and non-promotional education?
A. I think I can --
Q. Strike that. Dr. Kessler, in

Page 461

paragraph 194.2 --
A. Let me get there, please.
Q. -- you again -- in support of your opinion that Endo's promotional plans for Percocet included using medical education to market Percocet, you generally cite 1998 objectives from Ms. Kessler -- from Ms. Kitlinski? I apologize.
A. In 194.2?
Q. That's right. Just so you have it in front of you, I show you what's been marked as Kessler 13.
(Exhibit Kessler-13 marked for identification and attached to the transcript.)
BY MR. DAVIS:
Q. This is the document cited in paragraph 194.2.
MR. RAFFERTY: Mr. Davis, I think you just misspoke. You said 1998.
MR. DAVIS: Oh, I'm sorry, 19- --
MR. RAFFERTY: I think you mean 1999.
MR. DAVIS: That's right, thank

Page 462

you. 1999.
Q. And again, these are Ms. Kitlinski's objectives for 1999, right?
MR. RAFFERTY: Object to the form.
A. Yes.
Q. Okay. You don't know whether she achieved any of these objectives, do you?
A. I only know these are the objectives, sir.
Q. Okay. You don't know whether these objectives are the same as Endo's corporate objectives, correct?
A. Give me a second, if I can just review this for a second.
These would appear to be consistent with the corporate goals.
Q. What's the basis of your opinion that these are consistent with the corporate goals?
A. I've seen, for example, statements by -- and I have to match up dates -- but, for example, Carol Ammon talking about the corporate strategy of Endo, has said publicly that getting physicians to be acquainted with

Page 463

our products, but more importantly, it's getting physicians who are thought leaders that would not only talk about our products, but would really start to move the whole market towards a change in pain management. That was articulated as one of the major corporate goals and strategies by I believe the CEO at the time.
And certainly in a number of the bullets that I am reviewing on this document, these seem to match up. I'm happy to go into more detail about some of these bullets if you'd like.
Q. What are you reading from there, Dr. Kessler?
A. That is a transcript of a public statement by Ms. Ammon.
Q. Is that part of your reliance materials?
A. I'm sure -- I'm sure that is in my report at some point. It's publicly available on YouTube. You can go watch it.
Q. And that whole sheet that you're looking at, what is that? Did you prepare that

Page 464

yourself?
A. Yes. This is mine. I did ask someone to type -- to sit there in front of the YouTube as I was listening to the -- to the video, so that I didn't type that. This is your document. This is all my handwriting.
MR. DAVIS: I believe this request was made yesterday. But to the extent that Dr. Kessler is going to be relying on documents in front of him during the course of his testimony, I think it's improper for him to do that without those documents having been provided to us.
MR. RAFFERTY: I believe they're all on -- they're all on the reliance list.
MR. DAVIS: His handwriting is all on the reliance list?
MR. RAFFERTY: You can get his notes, but there's nothing wrong with him making notes and relying upon it. You can get copies of them.
MR. DAVIS: That's my request, and

Page 465

I think it was made yesterday. I think it's improper for us not to have them in advance of the deposition.
MR. RAFFERTY: Well, I disagree. He can make whatever notes he wants and bring them in, and you're entitled to have them, but there's no rule that says you can get them, you know, days in advance, his notes, I mean --
MR. DAVIS: Well, we can take up that discussion later on. But I'll renew the request that we get copies of the notes that Dr. Kessler is relying on during the course of his testimony.
MR. RAFFERTY: You're more than welcome to.
MS. FREIWALD: May we --
MR. DAVIS: I think the request is, correct me if I'm wrong, that we actually mark these notes as an exhibit. I think we've got a sticker here that we can use to do that. So we can mark at least these right now as Kessler-14.
THE WITNESS: Tell me where you'd

Page 466

like me to put it this.
MR. DAVIS: You can put it on a place that's not going to obstruct that --
THE WITNESS: Thank you, sir.
MR. RAFFERTY: You should put it on whatever the front page is. Oh, there it is. Okay.
(Reporter interruption.)
(Exhibit Kessler-14 marked for identification and attached to the transcript.)
MS. FREIWALD: Get the whole stack.
MR. DAVIS: That's the Endo stack. I think maybe when we go on a break, we can sort of figure out marking the whole and we can introduce them in the next one.
MS. FREIWALD: Yes.
BY MR. DAVIS:
Q. All right. So Ms. Ammon's -- the testimony for -- or the commentary from Ms. Ammon that you just read doesn't include every single bullet point here in

Page 467

Ms. Kitlinski's 1999 objectives, correct?
A. She doesn't --
Q. Right?
A. Well --
Q. It's a really easy yes or no.
A. Give me a second. Let me read every bullet point and then answer your question.
Q. Dr. Kessler, look at the quote on the page from Carol Ammon. Does that look anything like all of the bullet points in the exhibit that you're filibustering and reading right now?
MR. RAFFERTY: There's no filibustering. You asked him about whether or not the quote is contained in it. It certainly could be contained as a summary in it. It could be -- he's got a right to read the document you're asking him about.
A. Let me tell you the question -- what I need to determine. I need to know whether all these -- every bullet here is encompassed by Ms. Ammon's -- that's what I

Page 468

would look to determine --
Q. That's not my question, Dr. Kessler.
MR. RAFFERTY: That was your question.
MR. DAVIS: It was not my question.
Q. Is every single bullet point in Ms. Kitlinski's 1999 objectives included -- the bullet points included in the quote you read from Ms. Ammon?
A. Is it encompassed -- when you say "included," I'm sorry --
Q. I said "included," "specifically included." Not "encompassed" but "specifically included."
A. The concept?
Q. No, the specific bullet points. Are these specific bullet points --
A. The exact words?
Q. Yes. The specific bullet points, are they in that quote from Ms. Ammon?
A. These words are not the exact same --
Q. Thank you.

Page 469

A. -- as Ms. Ammon's.
MR. WEINBERGER: There's no reason to get upset. Everybody can be civil.
MR. DAVIS: Pete, enough. Why are you here?
MR. WEINBERGER: Why am I here?
MR. RAFFERTY: Wow, are you kidding me?
MS. AMINOLROAYA: Getting (inaudible), Josh. Can't control yourself.
THE WITNESS: Do me a favor, please. When counsel is -- call me back in the room when people are not --
MR. DAVIS: We can go off the record if there's any discussion you want to have.
THE WITNESS: Please have this off the record.
VIDEO OPERATOR: 8:45, we are off the video record.
(Recess from 8:45 a.m. until 8:52 a.m.)
VIDEO OPERATOR: 8:52, we are on

Page 470

the video record.
BY MR. DAVIS:
Q. Dr. Kessler, on page 118 of your report, you offer an opinion regarding Endo's marketing strategy and the increased risks of respiratory depression and abuse, correct?
A. Correct.
Q. And in support of that opinion on page 119 in paragraph 200.3, you refer to a 2002 Percocet sales representative detail aid, correct?
A. I'm sorry, which paragraph number? I lost you.
Q. 200.3 on page 119.
A. 200.3. I do, sir.
Q. Okay. You know that that piece was submitted to DDMAC for review, correct?
A. I'd want to double-check. I have no reason to dispute that.
Q. Okay. And you know that FDA never sent Endo an untitled letter regarding that promotional piece?
A. I'd want to check, but I don't believe so.

Page 471

Q. You know that Endo -- or FDA never sent Endo a warning letter regarding that promotional piece, correct?
A. I don't -- I don't believe they did.
Q. You know that FDA never took any enforcement action against Endo with respect to that promotional piece, correct?
A. I believe that's correct, but I'm not sure FDA ever reviewed it.
Q. And in fact, Dr. Kessler, you know that FDA never sent Endo a single untitled letter regarding any of its marketing of Percocet, correct?
A. I have their untitled letters -- I have their letters and all their -- all the letters here. I'd want to review them. I think there are comments on pieces, but I'd want to -- I'd want to double-check that.
Q. Well, you're not aware of any untitled letter that FDA ever sent Endo regarding its marketing or promotion of Percocet, correct?
A. On top of mind right now, I don't.

Page 472

I have them in my binder. I'd have to check.
Q. If you could check on a break, that would be -- I'd appreciate that.
You're not aware of any warning letters that FDA sent Endo regarding its promotion of Percocet, correct?
A. I believe that's correct. I don't see any warning letters.
Q. And you're aware that FDA never took any enforcement action against Endo regarding its promotion and marketing of Percocet, correct?
A. That's correct.
Q. In paragraph 200.1 -- or 201.1 on page 119 of your report, you refer to a 2002 Endo incentive compensation plan, correct?
A. Correct.
Q. You don't know whether that incentive compensation plan was ever utilized, do you?
A. Sitting here today, I don't know that answer without more research.
Q. I want to go back to the promotional piece, the Percocet promotional

Page 473

piece you cite in paragraph 200.3 on page 119.
A. Can you give me a copy? That would be great.
Q. It's on your report.
THE WITNESS: Gerard, can I have my book?
Q. I'm not going to ask you about the substance of the piece --
A. Okay.
Q. -- Dr. Kessler.
A. Thank you.
Q. So you don't know, Dr. Kessler, whether this promotional piece was -- you don't have any evidence that this promotional piece was shown to any prescriber in Cuyahoga or Summit County, Ohio, correct?
A. Sitting here today, I don't -- I don't know the -- the -- it's 200.3? I just want to see the piece, if I may.
Q. What is looking at the piece, Dr. Kessler, going to tell you about whether it was shown to any doctor in Cuyahoga or Summit County?
A. There's certain piece --

Page 474

MR. RAFFERTY: He's entitled to look at the document.
MR. DAVIS: I just asked him a question.
MR. RAFFERTY: I'm objecting because the witness is entitled to look at a document you're asking him about.
Q. What is looking at the promotional piece -- again, Dr. Kessler, what is looking at the promotional piece going to tell you about whether it was shown to any doctor in Cuyahoga or Summit County?
A. I'm interested whether it was a homemade piece or whether it was a national piece, and that could affect my appraisal of that answer.
Q. If I represent to you it's a national piece, what's your answer?
A. If it's a national piece, which it looks like, I have no reason to believe there was anything different with Cuyahoga County than nationally, but I don't know exactly who saw it in Cuyahoga.
Q. Yeah, you have no evidence of any

Page 475

particular doctor being shown that promotional piece in Cuyahoga County or Summit County, correct?
A. I think I answered your question.
Q. Well, I don't think you did.
You don't have any evidence that any doctor in Cuyahoga County or Summit County saw that particular promotional piece, correct?
A. I know that the piece was a national piece, and I know that the -- I know that the campaigns were done in Cuyahoga as they were done in the rest of the country. But I don't know who saw this in Cuyahoga.
Q. What is the basis of your knowledge about the extension of Endo's marketing campaigns into Cuyahoga County?
A. I have solely that -- his, I believe, testimony in depositions about the national scope of Endo's marketing.
Q. Page 120 and 121 of your report, Dr. Kessler, you offer an opinion regarding the benefits of Percocet with respect to quality of life, correct?
A. Let me just see. Paragraphs what,

Page 476

sir?
Q. On page 120 and 121, beginning with paragraph 204.
A. Correct, sir.
Q. Okay. And specifically you refer to in your report a detail aid in paragraph 205, correct? Again, I'm not going to ask you about the substance of the detail aid. There's no reason for you to go looking at it, Dr. Kessler.
A. Okay. So if it doesn't pertain to the detail aid, the question?
Q. You refer to a detail aid, correct, in paragraph 205?
A. And I just want to take a look at it, if I may. You don't have to give it to me.
I have the detail aid.
Q. And you're aware that that detail aid was submitted to DDMAC for review, correct?
A. I believe it was submitted. I don't know whether FDA reviewed it.
Q. You have no evidence that Endo ever received an untitled letter, warning letter, or received any enforcement action with respect to

Page 477

that promotional piece, correct?
A. I don't know whether FDA did anything -- I don't believe FDA did anything with this piece, to my knowledge.
Q. And that includes not sending Endo an untitled letter or a warning letter, correct?
A. Nor necessarily reviewing it, correct.
Q. And you describe in the preceding paragraph, paragraph 205, a single open label study that Endo relied upon in that promotional piece, correct?
A. I rely exactly what I -- that's correct.
Q. Did you review that study?
A. The -- just make sure. What study --
Q. 389, the single open label study.
A. Yes, I believe I did. I want to go back and check.
Q. Is your issue with that study the results of the study or the methodology used in that study?

Page 478

A. It doesn't constitute substantial evidence.
Q. So it's limited to the -- and that's -- in your opinion, that's because it's an open label study?
A. No. For several reasons.
Q. Does one of those reasons include the substance of the study -- does one of those reasons include the results of the study?
A. Sure. I mean, if you want to -- if you give me the study, I'm happy to discuss it.
Q. Beginning on page 122 of your report, Dr. Kessler, you offer some opinions regarding Endo's marketing and promotion of Opana ER, correct?
A. I do, sir.
Q. And in paragraph -- on page 124, paragraph 215.1, you refer --
COURT REPORTER: Is that 2-1-5?
MR. DAVIS: Sorry. 215.1.
Q. -- you refer to a 2002 Opana ER risk management presentation, correct?
A. Hold on one second, sir.
215.1 or 2? I'm sorry.

Page 479

Q. 215.1.
A. That risk management presentation, yes.
Q. Yes.
THE WITNESS: Gerard, can I get the binder with 215, please.
Q. Your report, Dr. Kessler, indicates that it's a 2002 risk management presentation, correct?
A. That's what my report indicates.
Q. You're aware, Dr. Kessler, that Opana ER was approved in 2006, correct?
A. I believe that's correct.
Q. And in paragraph 214, you also refer to a 2002 Opana ER marketing plan, correct?
A. That's exactly what that says.
Q. And again, in paragraph 215.2, you refer to a 2002 Opana ER marketing plan, correct?
A. Which paragraph, sir?
Q. 215.2.
A. Yes. I believe I answered that question, that that was dated 2002. I can

Page 480

confirm on the document, if you'd like.
Q. And again, you're aware that Opana ER was approved in 2006, correct?
A. That's correct.
Q. So at least this portion of your opinion regarding Endo's marketing strategy for Opana ER is based upon documents created four years before the launch of the product?
A. Let me just check.
These -- that's correct with regard to these -- with regard to these paragraphs.
Q. Okay.
A. And Ms. Kitlinski's title is on 216.2. I just didn't remember it.
Q. Again, there you cite e-mail correspondence from Ms. Kitlinski from 2003, correct?
A. That's exactly correct.
Q. And additional correspondence from -- in paragraph 216.5, correspondence from Vin Tormo from 2003, correct?
A. That's exactly what I cite.
Q. And those e-mails were three years -- dated three years prior to the launch

Page 481

of Opana ER, correct?
A. That's exactly when these e-mails are dated.
Q. So at least this portion of your opinion --
A. Hold on a second. My microphone disappeared. I apologize. Sorry. I apologize.
Q. So at least this portion of your opinion regarding Endo's marketing strategy for Opana ER from paragraphs 214 through 216.6 are all based on documents that are either four -- three or four years earlier than the approval of the product you're opining on, correct?
A. Exactly, sir.
Q. With respect to the 2002 Opana ER marketing plan described in paragraph 214, again, you don't know whether that was the final marketing plan, correct?
A. All I know, it doesn't say draft or doesn't have a -- doesn't seem to be a draft copy. That's all I know. I can't characterize it the way -- I couldn't characterize it as final. But it doesn't say draft.

Page 482

Q. Dr. Kessler, beginning on page 129, at paragraph 218 --
A. Yes, sir.
Q. -- you refer to a product named Numorphan?
A. Yes.
Q. You're aware that Numorphan is an IR opioid product, correct?
A. Yes, I do.
Q. And Opana ER is an extended release product; is that right?
A. Fair.
Q. And in your report -- let's flip back a bit. Page 109, paragraph 184.
A. Yes.
Q. You state that between 1997 and 2008, Endo promoted or sold various opioid products, including Percocet and Opana Extended Release, correct?
A. That's correct.
Q. You're aware that Numorphan was removed from the market well before 1997, correct?
A. Yes. The blue -- the blue pills.

Page 483

Q. You've not reviewed all of the correspondence with FDA regarding the removal of Numorphan from the market, have you?
A. I've read some of the history of it. I wouldn't want to represent that I've looked at everything. I'm not sure the record has everything.
Q. You weren't at the FDA when Numorphan was withdrawn from the market, correct?
A. I don't believe so.
Q. You can't speak to the specific circumstances regarding the withdrawal of Numorphan from the market, can you?
A. Did you say -- sure. There was very significant concerns about abuse. I'm not sure I'm missing -- this was a very highly potent product that was being extensively abused. One of the most potent compounds known to man.
Q. And your opinion about that is based on a May 2000 drug intelligence brief from the DEA Philadelphia division?
A. What --

Page 484

Q. In paragraph 218.1.
A. No. I've read a lot. There's an entire historical record. This is a pretty famous drug abuse history issue. And this has been cited and discussed in many books. And I've read a part of this.
So it's not just -- my knowledge isn't based just on that. That may be what I cite here to try to summarize the history, but I've read other history about these, quote, blue pills.
Q. Is your knowledge about the withdrawal of Numorphan based on anything not cited in your report or your reliance materials?
A. Maybe my general knowledge -- my general education.
Q. You're aware, Dr. Kessler, that since its launch in 2006, Opana ER has always -- the label for Opana ER has always contained a black box warning?
A. I believe so, yes, of course.
Q. And the black box warning indicated that Opana ER contained oxymorphone?

Page 485

A. If you can show me the black box warning. But of course, it -- I mean, I'm sure -- I just want to make sure what's in the black box warning as opposed to what's next to the black box warning. But I'm pretty sure that's correct.
Q. Dr. Kessler, I realize the label for Opana, like other opioid products, has changed over time.
(Exhibit Kessler-15 marked for identification and attached to the transcript.)
BY MR. DAVIS:
Q. I'm showing you what's been marked Kessler-15. This is the Opana ER -- this is the Opana ER label from 2009.
A. Thank you, sir.
Q. And you can see there that the black box warning reads, Opana ER contains oxymorphone, correct?
A. That's exactly what it says.
Q. With an abuse liability similar to other opioid analgesics, correct?
A. Correct.

Page 486

Q. Oxymorphone can be abused in a manner similar to other opioid agonists, correct?
A. You read it correctly.
Q. Legal or illicit, correct?
A. Correct.
Q. You're aware that all of Endo's promotional materials for Opana ER contain the black box warning, correct, for Opana ER?
MR. RAFFERTY: Object to the form.
A. I don't -- I don't -- depend on how you define "materials."
Q. You've not reviewed every single Opana ER promotional piece, have you?
A. No. I don't think any -- no. I don't think -- I think that would be a fair statement.
Q. In fact, you cite five Opana ER promotional pieces in your report, correct?
A. I'd have to go back and check. I don't know -- I haven't counted it up.
Q. I can represent to you that there are five Opana ER promotional pieces cited in your report.

Page 487

Are you aware, Dr. Kessler, that there are thousands of Opana ER promotional pieces?
A. I'm sure that -- I'm aware there's numerous ones. I don't know the exact number.
Q. And of those thousands, you cite only five in your report, correct?
A. I cite what I cite, and I reviewed what's on my reliance list.
Q. On page 221 -- I'm sorry -- page 132, paragraph 221.1 --
A. 221. --
Q. 1.
A. Thank you, sir.
Q. -- you refer to a number of awareness trial and usage studies, correct?
A. Yes.
Q. ATU studies is what you refer to them as?
A. Yes, exactly.
Q. And these are reports of doctors' perceptions about a product, correct?
A. That's exactly what -- actually, if you -- we should actually probably pull the

Page 488

reports so I can be exact. But I think you're generally correct.
THE WITNESS: Gerard, can I have 221, please.
Just give me one second.
You have it? Or I can try to pull it up.
Go ahead, sir. You can ask your question.
Q. My question was only that these ATU studies reflect physician perceptions of a particular product, correct?
A. I believe that's in the -- on the document. I believe that. But I'd want to have the document in front of me, and I'm just having trouble finding it. But that's my recollection exactly, sir.
Q. And doctors' perceptions can be based on any number of things, correct?
A. Yeah, I'm not sure that's exactly correct. I mean, they certainly can be affected by a number of things.
Q. Doctors get information from places other than pharmaceutical promotional

Page 489

marketing, correct?
MR. RAFFERTY: Object to the form.
A. They can.
Q. And they do?
MR. RAFFERTY: Object to the form.
A. Depends. We don't know in any specific instance. You'd have to be more specific.
Q. On page 135 of your report, paragraph 224.1, Dr. Kessler, you refer to a 2009 Opana ER savings card and resource kit, correct?
A. Yeah. Let me just pull that up, if I can.
Q. Do we have a copy? I can give you a copy.
A. Let me pull up my notes on that, because I think it is --
MR. RAFFERTY: Thank you.
What number is this, Josh?
MR. DAVIS: This is --
(Exhibit Kessler-16 marked for identification and attached to the transcript.)

Page 490

BY MR. DAVIS:
Q. I'm showing you what's been marked as Exhibit 16.
A. I have it, sir.
Q. So we've got it for the record, there's Exhibit 16 for you?
A. Thanks an awful lot, sir.
Q. You're aware, Dr. Kessler, that this document was submitted to DDMAC?
A. It may have been sent in. I don't believe -- I don't believe it was reviewed.
Q. You're not aware -- do you know one way or another whether FDA reviewed this particular piece?
A. I'd have to double-check, but I don't believe so. But I don't see any specific comments, and I would be surprised -- it would surprise me if they did. I'd have to double-check the answer to that question.
Q. FDA doesn't provide comment on every single piece it reviews, correct?
A. Your point is exactly -- in fact, what you see is, there's umpteen things that are sent in. FDA doesn't have the resources.

Page 491

In fact, at this time, there were very limited resources, and there are only a handful of reviewers. So that's impossible.
Q. You can't tell me -- you know that Endo never received an untitled letter regarding this promotional piece, correct?
A. It should have, but I don't believe it did.
Q. You know that Endo never received a warning letter regarding this particular promotional piece marked as Exhibit -- Kessler Exhibit 16, correct?
A. That's correct, but it should have. There's no question that this piece should have stimulated a warning letter. It is clearly problematic, when you're giving out coupons, to downplay an addiction risk.
Q. Dr. Kessler, the fact remains, Endo never received an untitled letter or warning letter regarding this piece, correct?
A. I wish FDA had the resources to call your company on this. It did not receive -- FDA didn't have the resources. The piece is outrageous.

Page 492

Q. Endo never received a warning letter or untitled letter about any of the Opana ER promotional or marketing activities, correct?
A. I believe I've -- I believe I've answered that question.
Q. You haven't. You actually answered that question with respect to the other Endo product you refer to in your report, which is Percocet.
Specifically with respect to Opana ER, Endo never received an untitled letter or warning letter from FDA, correct?
A. That's correct.
Q. FDA never undertook any enforcement action against Endo with respect to its marketing or promotion of Opana ER, correct?
A. That's correct. But this piece is an example where it should have.
Q. Were you the head of DDMAC during your time as head of FDA, Dr. Kessler?
MR. RAFFERTY: Object to the form. This was all gone over.
You can answer.

Page 493

A. DDMAC reported to me.
Q. You weren't the head of DDMAC during your time at FDA, correct?
MR. RAFFERTY: Object to the form.
A. It reported to me. Depends what you mean by "head." It had its director. That director reported to me. And I was intimately involved with that division.
Q. Your title was never director of DDMAC, was it?
A. I was Commissioner of FDA.
Q. Page 135 of your report, paragraph 224.2, you refer to --
A. I'm sorry. 224.2?
Q. 224.2.
A. Yes.
Q. Dr. Kessler, you testified that FDA did not send a warning letter because it lacked resources, correct?
A. I think I testified that it did not send a warning letter, period. It lacked resources, period.
And certainly on coupons, you shouldn't downplay the risk of addiction,

Page 494

period.
Q. So you don't know exactly why FDA didn't send a warning letter with respect to that piece or any piece?
And when I say "that piece," I mean the promotional piece marked Kessler-16.
A. We don't have a record to answer your question.
Q. Okay. So anything you say is just a guess about whether a warning letter -- why a warning letter was not sent, correct?
MR. RAFFERTY: Object to the form.
A. No. It's based on my experience, and I've been there, and I know the resources, and I know the reality.
Q. But specifically, you don't know why FDA did not send a warning letter with respect to any particular piece, correct?
MR. RAFFERTY: Object to the form, asked and answered.
A. Again, the record, I think, doesn't reflect that with regard to this piece.
Q. Or any particular piece that I've put in front of you regarding Opana ER or

Page 495

Percocet, correct?
A. I don't think we have the internal FDA record here.
Q. So you don't know exactly why FDA did not send a warning letter or untitled letter regarding any of those pieces I've put in front of you?
MR. RAFFERTY: Object to the form, asked and answered.
Q. The answer is?
A. I believe I answered that question.
Q. When? Let me ask it again just so the record is clear, because I got an objection and no answer.
So you don't know exactly why FDA did not send a warning letter or untitled letter regarding any of the Opana or Percocet pieces I've put in front of you?
A. I don't know exactly why in this instance.
Q. Thank you.
A. But -- I don't know exactly why in this instance.
MR. RAFFERTY: Are you done?

Page 496

THE WITNESS: I'm not. I could expand. But I'll be short.
Q. On page 139 of your report, paragraph 231.2 --
THE WITNESS: Gerard, please.
MR. RAFFERTY: I'm sorry. What paragraph?
MR. DAVIS: 231.2.
(Reporter interruption.)
A. 231.2?
Q. Yes, please.
A. Thank you, sir. Just give me one second.
Yes, sir.
Q. You refer to, in paragraph 231.2, what you describe as an Endo-sponsored brochure entitled Understanding Your Pain, correct?
A. I have it in front of me, sir.
Q. And you refer to this piece in support of your opinion regarding the risks of respiratory depression, addiction, and abuse, correct?
A. With regard to higher doses, yes, specifically.

Page 497

Q. You know the date of the piece that you refer to in paragraph 231.2 is dated 2004, correct?
A. That's when it's copyrighted, sir.
Q. It's two years before the launch of Opana ER, correct?
A. That's correct. That copyright date is before.
Q. And again, you're not aware of Endo ever receiving any untitled letter or -- strike that.
I want to talk a little bit, Dr. Kessler, about the promotion of reformulated Opana ER.
Are you familiar with reformulated Opana ER?
A. I do. I am familiar. Let me just get it.
Q. And in particular, in --
MR. RAFFERTY: I'm sorry. Are you done with this?
MR. DAVIS: Yes.
Q. Paragraph 159 -- I'm sorry. Paragraph 257 on page 159 of your report,

Page 498

Dr. Kessler.
A. Paragraph 257?
Q. Yes.
THE WITNESS: Gerard, please.
A. Yes, sir.
Q. You reference Endo's launch materials for Opana ER, which include the phrase, and I quote, designed to be crush-resistant, close quote, correct?
A. That's correct.
Q. You're aware that Endo submitted its launch materials to FDA for review, correct?
A. I am.
Q. You're aware that FDA actually reviewed these launch materials, correct?
A. I'm not sure I have a -- I'd have to go back --
MR. RAFFERTY: Object to the form.
A. If you have comments, you can give them to me, please.
Q. Do you know --
A. I mean, I can find the comments if you -- I can go find them, or you can give me

Page 499

their comments.
(Exhibit Kessler-17 marked for identification and attached to the transcript.)
BY MR. DAVIS:
Q. Let me show you what's been marked as Kessler Exhibit 17.
And you're aware, Dr. Kessler, that in FDA's comments regarding Endo's launch materials, nowhere do they say that Endo should remove the phrase, quote, designed to be crush-resistant, from its launch materials, correct?
A. It was not caught by FDA, no.
Q. FDA offered other comments, correct?
A. Yes.
Q. Okay. But they didn't specifically say, remove that from the promotional piece; correct?
A. There are documents that talk about not discussing the physiochemical properties, which is, in essence, the same thing. But I'd have to have those.

Page 500

Q. Are you familiar with Dr. Hertz?
A. Sure. I'm not sure I know her, but --
Q. Who is Dr. Hertz?
A. Sharon Hertz.
Q. And was she employed by the FDA at any point?
A. Yes.
Q. Do you know what her role at FDA was?
A. She was, I believe, division director at one point.
Q. Okay. And are you aware of Dr. Hertz offering commentary on the appropriateness of promotional comments regarding the design or the intent of an abuse-deterrent product?
A. I'd have to --
MR. RAFFERTY: Object to the form.
A. I'd have to review her entire record or comments.
MR. DAVIS: So I'm going to mark here as Exhibit 18 Endo's submission of its reformulated Opana ER promotional

Page 501

materials.
(Exhibit Kessler-18 marked for identification and attached to the transcript.)
BY MR. DAVIS:
Q. This is just an excerpt. We have the complete -- oh, I'm sorry, Dr. Kessler.
A. Thank you.
Q. I have the complete submission, if you think it would be helpful just for context, but it's massive.
A. Yeah, no, this is -- I appreciate that. Just give me one second, if I can. Let me just get oriented for a second. Just give me a second.
Sir, you handed me Kessler-18.
Q. Yes. And I want to point you -- these are the materials that Endo submitted to FDA. It's the reformulated Opana ER launch materials.
And on page 2 -- it's Bates number that ends in 897 --
MR. RAFFERTY: I don't have that. It goes from 8- -- unless it's just out

Page 502

of order.
A. I have 897.
MR. RAFFERTY: Mine is out of order.
MR. DAVIS: I'm sorry about that.
Q. So here, Endo writes -- provides substantiation for its claim of designed to be crush-resistant.
A. I'm sorry. On page 897?
Q. Yeah. It runs from 896 to 897.
A. So the examples of public commentary?
Q. Yes. And included -- it's the third one from the bottom bullet point -- is Dr. Hertz's statement during advisory committee deliberations regarding marketing use of designed to be, correct?
Is that what that reads?
A. I'm not sure. It's a little out of context for me. If you can give me that, Dr. Hertz's -- do you have Dr. Hertz's statement?
Q. Dr. Hertz's statement is two pages behind.

Page 503

A. So it's a different document.
Q. It was included in the full submission. What you've got is an excerpt of the launch materials submission.
MR. RAFFERTY: I'm sorry, Josh. Where are you quoting from on 896?
MR. DAVIS: So it just runs from here, and then you go to the next page, and it's the third bullet from the top -- bottom.
MR. RAFFERTY: Yes.
MR. DAVIS: Dr. Hertz's -- the reference to Dr. Hertz.
MR. RAFFERTY: I got you.
MR. DAVIS: And then if you go two pages past, we have Dr. Hertz' actual statement.
MR. RAFFERTY: Got you.
Q. Do you see that?
A. Just give me one second, please.
I see Dr. Hertz's statement.
Q. And Dr. Hertz, who at the time is a senior FDA employee, said during the AdCom that, The other thing we've decided would be

Page 504

acceptable to say in marketing is that the product was designed to be or was -- the design is intended to be abuse-deterrent. Correct?
A. That's what Dr. Hertz says at this moment in time.
Q. Okay. You can set that aside.
A. Can I just give -- I've taken this out of order. I apologize. Can I give you this?
Q. We can fix that.
A. I apologize.
Q. That's no problem.
Dr. Kessler, your report cites to a number of third-party materials ostensibly funded by Endo, correct?
A. We can -- I'm not sure the word "ostensibly." We have the funding. We know funding. So those are -- so without that word, yes.
Q. Do you know -- did you review any of the grant agreements by which Endo provided the funding you describe in your report?
A. I may have. I'd have to go back and review specifically.

Page 505

Q. If you had, would it have been in your reliance materials?
A. If I relied on it -- I'm looking at a lot of documents on the computer, so I don't want to say the reliance looks at every document that I looked at on the computer. That's impossible.
But I was certainly searching for and went through the NIPC, for example, documents on the computer. But the reliance list should have the things that I'm relying on.
Q. You're familiar with the Accreditation Council for Continuing Medical Education, ACCME?
A. Intimately, and happy to discuss it.
Q. And you're familiar with the ACCME guidelines?
A. And which ones? What date? Which ones?
Q. 2002.
A. If you want to give me them -- I would appreciate if you'd give me those.

Page 506

Q. Can we talk about them at a general level?
A. Sure.
Q. Would you agree -- when you said you're intimately familiar with the ACCME --
A. But I'm not familiar with -- there's different versions, and there's different points in time in the history of ACCME.
Q. Are you aware of any point from 1998 on that the ACCME guidelines controlled -- permitted a donor to control the content of continuing -- independent continuing medical education?
A. It's complicated.
Q. Are you aware of any point in time since 1998 where the ACCME guidelines permitted the donor to have control over the content of continuing medical education?
A. Again, I think it's a complicated answer to that question.
I think those guidelines, certainly as interpreted -- as pharma did them, there were different extensive control that -- again, we can discuss whether they violated the policy or not. There's a lot of ways to exert control.
Q. Your report refers to NIPC?
A. Yes.
Q. Okay. Are you aware of NIPC ever losing ACCME accreditation?
A. Sitting here today, I am not, top of my head. I don't give that any credence, though.
Q. Your report also refers to the American Pain Society, APS, correct?
A. Yes.
Q. Are you aware of APS ever losing its ACCME accreditation?
A. I'm not. But again, I don't give that any credence.
Q. Your report refers to AAPM. You're familiar with that organization?
A. Yes.
Q. That's the American Academy of Pain Management; is that right?
A. Yes, sir.
Q. Okay. Were you ever aware of AAPM ever losing its ACCME accreditation?
A. Same answer. I'm not, as I sit here. But again, I don't give it any credence.
Q. Are you familiar with the American Pain Foundation?
A. Yes.
Q. And you refer to that in your report?
A. I do.
Q. Are you aware of APF, the American Pain Foundation, ever losing its ACCME accreditation?
A. It certainly should have.
Q. Did it?
A. I'd have to go back and review the record.
Q. You're not aware of it ever losing --
A. Correct.
Q. -- its ACCME --
A. Correct.
It certainty should have. I think there's no question about that.
Q. I just want to make sure I get this

Page 507

Page 508

Page 509

question in before the answer.
You're not aware of APF ever losing its ACCME accreditation, correct?
A. That's correct, as I -- as I sit here today, without further research.
Q. Dr. Kessler, I think you testified yesterday that you're not here as an expert in DEA regulations. Is that right?
MR. RAFFERTY: Object to the form.
A. The Court can determine what I have expertise on, or others can determine what I have expertise.
I probably have, you know -- certainly, as -- as it relates to DEA/FDA interactions, I probably have a good deal of expertise in that, and probably more so than almost anyone, when comes to FDA/DEA. I certainly have it.
I think it's fair to say -- I certainly hope that others will testify about DEA. I can help the Court, I mean, on things that I do have expertise that relates to controlled substances and the national strategy, including DEA.

Page 510

Q. Which doesn't include suspicious order monitoring?
A. Well, there is suspicious order monitoring of manufacturers, sir, that applies to the manufacturers, and I think I'll leave that primarily to others.
I certainly wouldn't talk to distributors, but I'm happy to discuss a little with regard to the manufacturers.
Q. You're not an epidemiologist, are you, Dr. Kessler?
A. I'm a professor of epidemiology.
Q. Dr. Kessler, yesterday -- and I don't want to get into the specifics, but yesterday, you referred to two instances where companies with whom you were affiliated addressed things that, I think as you described it, were out of regulatory compliance.
Do you recall that testimony?
A. Or potentially, yes.
Q. And you cited to two particular instances, correct? Do you recall that?
Again, I don't need -- I'm not going to ask you about the specifics, but do

Page 511

you recall?
A. Yes, I do.
Q. And you testified that you worked with the company to work through those issues, correct?
A. Yes.
Q. Okay. And you did so at the board level; is that right?
A. Yes.
Q. Okay. One of the issues -- compliance issues that you worked through was identified externally.
Do you recall that?
A. One had an external component.
Q. Fair.
And the other was identified internally, correct?
A. Correct.
MR. RAFFERTY: Objection. This has all been gone over and asked and answered.
Q. And you would agree that it was important for those companies to work through those compliance issues, correct?

Page 512

A. Of course.
Q. And to address those compliance issues, correct?
A. Of course.
Q. And would that apply equally to any regulatory compliance issue you, yourself, had identified for those companies? Correct?
A. Sure. Individual board members -- I'm not sitting there identifying individual issues; I'm at a board level. So it's a little more complicated than -- you know.
I don't want to give you a sense that I'm working as -- I mean, these are -- this is privately held -- you're familiar with that -- and I'm on a board. This is at a board level.
Q. Fair, Dr. Kessler.
I'm not suggesting that in your role as a board member, you have a responsibility to monitor, but --
A. There is some monitoring, but I just want to give -- there's a board role, and there's a -- regulatory operations, and those are different. That was my only point.

Page 513

Q. In your role as a board member --
A. Yes.
Q. -- if you become aware of a regulatory compliance issue, you would agree, Dr. Kessler, that it's important for that issue to be addressed, correct?
A. Absolutely.
Q. Okay. Including at the board level, right?
A. I wouldn't say, if I became aware of an issue, that I would bring it necessarily to the full board. I may bring it to the compliance committee. I may bring it to the director of regulatory affairs. It depends on the seriousness of the matter.
MR. DAVIS: Can we take a five-minute break? I've got limited time. I just want to organize it. Really, five minutes, if that's okay.
MR. RAFFERTY: Sure.
VIDEO OPERATOR: 9:43, we are off the video record.
(Recess from 9:43 a.m. until 9:57 a.m.)

Page 514

VIDEO OPERATOR: 9:57. We are on video record.
BY MR. DAVIS:
Q. Dr. Kessler, page 121 of your report --
A. Give me a second, please.
Q. Sure.
-- heading number 4 --
A. Yes.
Q. -- you state, As reports of Percocet abuse grew, Endo's promotion and sales of Percocet increased, correct?
A. Yes.
Q. You're not offering any opinion that Endo's promotion caused the reports of Percocet abuse to grow, correct?
MR. RAFFERTY: Object to the form.
A. Oh, sure, I am.
Q. And is your opinion that Endo's promotion caused the reports of abuse to grow?
MR. RAFFERTY: Object to the form.
A. Sure, I am. Yes, of course.
Q. And please describe the methodology you used to determine that Endo's promotion

Page 515

caused reports of Percocet abuse to grow.
A. We know the ROI of a promotion. We know the corporate strategy involved in promotion. We know that is to increase the number of pills, amount of drug in interstate commerce.
As Dr. Sackler, I think, aptly stated in her distribution, too much drug in interstate commerce, too much sales leads to the epidemic. That's what happens.
There is further methodology. There is published studies by Dr. Wright at Purdue that does the analysis that corresponds to the number -- to the amount of drug in interstate commerce, the number of prescriptions sold, and abuse. That is established.
So if you engage -- if you sell more drug in interstate commerce, and that is the result of promotion -- and those things, I think, we established yesterday. I think everyone certainly agreed that it was promotionally sensitive -- promotionally sensitive, increased drug and interstate

Page 516

commerce -- more drug and interstate commerce, more abuse.
Q. Is that your complete methodology for determining -- for your opinion that Endo's promotion led to an increase in reports of Percocet abuse?
MR. RAFFERTY: Object to the form.
A. I won't use the word -- that's the general logic train. It is pretty simple when you study it, but there's obviously -- if you look -- we can discuss the methodology to determine how prescriptions are linked to abuse and how those numbers -- in that methodology, those are in those published studies, and we certainly have a very strong record, I believe, that promotion is -- these drugs are promotionally sensitive.
Q. Are all of those studies that you just described cited in your reliance materials?
A. Sure. They're not described; they're listed.
Q. Is there anything in your report describing the specific -- the methodology

Page 517

specific to Percocet?
A. Well, the Percocet section certainly deals with the promotional activities and the promotional goals and I believe their sales numbers. So those things -- that data is in the report.
Q. So your methodology as it relates to Percocet is based on the promotional activities described in your report as it relates to Percocet?
MR. RAFFERTY: Object to the form.
A. So yes. I think we all have to recognize -- and I'm happy if your client can -- it's somewhat limited because of the dates on Percocet. But I have -- with the record that I have in front of me that you've produced on Percocet, yes, that's what I based the decision -- that's what I -- that's what I based the logic on and my conclusions.
Q. In paragraph 207, the first line, you write, After receiving FDA approval to market additional strengths of Percocet in 1999, Endo's promotional budget of Percocet grew to $4,256,000 by 2003. Correct?

Page 518

MR. RAFFERTY: Object to the form.
A. That's what it says, yes.
MR. RAFFERTY: I'm sorry. I thought you -- okay. I thought you said -- sorry. I thought you misquoted. You didn't. That's my fault.
MR. DAVIS: No problem.
Q. If Endo spent half that amount to market Percocet, what would the impact have been on reports of abuse?
MR. RAFFERTY: Object to the form.
A. I have no opinion on that.
Q. You can't tell me what the reports of abuse would have looked like had Endo spent half that amount marketing Percocet, correct?
A. I've not done that analysis, no.
Q. You can't tell me what reports of Percocet would have looked like had Endo spent zero dollars on marketing Percocet from 1999 to 2003, correct?
MR. RAFFERTY: Object to the form.
A. Oh, certainly. I could -- I mean, I could certainly tell you that it would be less. We know these are promotionally

Page 519

sensitive. I've not done the quantitative analysis.
Q. You can't tell me how much less?
MR. RAFFERTY: Object to the form.
A. I've not done the quantitative analysis, no.
Q. And the same applies to Opana ER; you've not done any quantitative analysis that links the amount of Endo's marketing budget to specific reports of abuse?
A. So there is some data on Opana that we know that -- if I'm correct -- and I have to go back and look on your ROI from your promotional activities.
So the areas of the country that you targeted, right, and the program allocations were direct to the areas of greatest ROI, and I don't think I've done -- I do have some of that -- the program allocations for, for example, Ohio. But I have not done that specific quantitative analysis.
Q. So had Endo spent half the amount of money it did promoting Opana ER, you can't tell me what the rates of -- how that would

Page 520

have impacted the rates of abuse of Opana ER, correct?
MR. RAFFERTY: Object to the form.
A. Well, I think that would be fair because -- I mean, it's possible you could spend half and still have been even more effective. It depends what you're spending it on. So again, your question is a pretty general one.
Q. But you've not identified any specific link between the dollar amount spent on promotion and reports of abuse, correct?
MR. RAFFERTY: Object to the form.
A. Yes. I mean, there's clearly the link, if -- we know that promotion is linked, in your own documents, to ROI and increased prescribing. And we know that increased prescribing, more drugs in interstate commerce. And we have that methodology that Purdue did and others have done that links that. So yeah, there is a link.
Q. But you can't specifically quantify the relationship between a dollar spent promotionally and reports of abuse, correct?

Page 521

MR. RAFFERTY: Object to the form.
A. I've not done that analysis the way you've stated.
Q. And that analysis is nowhere in your report, correct?
A. Well, if I haven't done it, how could it be in my report?
Q. Dr. Kessler, you're aware that there was a risk map -- Endo put in place a risk map related to Opana ER, correct?
A. The drug would not have been approved without that, correct. It was a requirement of approval.
Q. To be clear, at that point in time, FDA did not have statutory authority to require a risk map, correct?
A. We could spend a lot of time discussing statutory authority. It may not have been -- there was not -- there were not REMS, I believe, on the 701. FDA had the authority to do risk maps, but again, we leave that to lawyers discussing that.
Q. Do you recall a discussion of the ATUs earlier with me, Dr. Kessler?

Page 522

A. You asked me about whether they reflected doctors' perceptions, is what I remember. And I didn't have the actual document in front of me, so I did it from memory.
Q. And those reports are referenced on page 132 of your report?
THE WITNESS: Gerard, can I just get back --
A. What paragraph are we talking about? Let me see if I can find the documents that you're talking about.
Q. Specifically paragraph 221.2?
A. Do you have the document that's referenced? It would be helpful because I'm not sure my notebook has it.
MR. RAFFERTY: 221, Gerard.
Q. 221.2.
A. I just want to see if I have 437.
I don't think I have --
THE WITNESS: Parvin, can you just help me see if I can find this document that's referenced -- that Mr. Davis is referring to? I just don't -- if you

Page 523

have it or can pull it up for me.
Q. Let's try it this way.
Dr. Kessler, your report quotes in paragraph 221.2 a June 2000 ATU study describing perceptions of, quote, low abuse potential.
Do you see that?
A. Yes. Just maybe I have it here. I think I have it. I see my paragraph, sir. I'm just trying to find that document.
Q. My question is, Dr. Kessler, whether you've seen -- you've not seen any Opana ER promotional piece that contained the phrase, quote, low abuse potential, correct?
A. I mean, I've seen it as far as in a doctor studies reports. Let me just see the range of promotional tools.
Q. I've tried to ask a very precise question, Dr. Kessler.
A. And I respect that, sir. I just want to get my answer -- give me a second to answer your question precisely.
So you asked me about materials, correct? Let me just see your question. Your

Page 524

exact question is, you've not seen it in a promotional piece.
What I've seen is reports of sales reps -- it says, Many were persuaded to try it because of rep persistence and information they provided and lower abuse potential.
But you're correct. I've seen that. I've certainly seen the time X reports in the promotional pieces which talk about time X, which certainly implies lower abuse potential. So I've seen that.
Q. Let's try it again.
You've not seen any Opana ER promotional piece that contains, quote, low abuse potential, close quote, those words exactly as I've just articulated?
A. You're correct. That's not how your company did it.
MR. DAVIS: Thank you, Dr. Kessler.
THE WITNESS: Thank you, sir, very much.
May I ask for a break? Thank you.
MS. LEVY: I didn't say we would give it to you; I said you may ask.

MR. RAFFERTY: Yes, you can take a break.

VIDEO OPERATOR: 10:13, we are off the video record.

(Recess from 10:13 a.m. until 10:25 a.m.)

VIDEO OPERATOR: 10:25, we are on the video record.

MR. DAVIS: Dr. Kessler, thanks for your time. I'm done with my questioning for right now.

I do want to reserve the right to conduct additional questioning, and object again for the record that the time allotted to defendants, and including Endo specifically, was insufficient, given the scope and content of your report.

THE WITNESS: Thank you, Mr. Davis, for your questioning.

MR. RAFFERTY: And just for the record, plaintiffs disagree.

EXAMINATION

BY MS. LAURENDEAU:

Q. Dr. Kessler, I'm Amy Laurendeau. I represent Janssen Pharmaceuticals. I'm going to use the time allotted to me to ask you about your numerous opinions regarding Janssen in your report and do the best we can to get through as many as we possibly can in the next few hours.

Okay?

A. Yes.

Q. With respect to Janssen, the opinions you're offering are limited to its three opioid products, Duragesic, Nucynta IR, and Nucynta ER, correct?

A. I think that's -- I think that's correct in general with regard to -- I think that's -- with respect to Janssen -- the reason I'm having a little trouble answering that question are some of the facts.

Janssen provided, for example, the narcotic for Purdue for OxyContin, and the facts in Janssen's own documents show that it drove the increase in oxycodone. I don't think that's an opinion; I think that's a fact.

So I just think that should be

on -- that's -- it's clear that, again, from the documents -- the budget documents in Purdue and Janssen's own documents from Noramco -- that you developed a super poppy that Purdue bought and, I think it's fair to say, in Janssen's own words, enabled oxycodone to -- the extent of oxycodone to be produced.

You also affect a significant amount of -- you're the number one narcotic raw material distributor in the world, so there are a lot of -- if we're talking about generic oxycodone and others, I have those sales figures.

So again, I think you're relatively right with opinions, but I just want to make sure the record reflects that these relationships among defendants are complex and interconnected, and Oxy would never have -- OxyContin would never have flourished the way it did but for Janssen.

Q. These aren't issues you intend to testify to at trial, though, are they?

A. I'll answer the questions that I'm asked.

Q. You haven't said a word about Noramco in your 300-plus page expert report, have you?

A. You're right. The documents are on my reliance list.

Q. In the 315 pages in which you've listed the facts and opinions to which you testified in this litigation, you haven't said anything about Noramco other than to list it as a defendant, correct?

A. I think -- I mean -- I think that's correct on the report. But certainly those documents are on my reliance list and things that I've considered.

Q. Are you intending to offer opinions about Noramco and API and Janssen's role with respect to production of API at trial? Yes or no. I need to know today.

A. I'm not -- I'm going to answer the questions that I'm asked. Those are facts. I don't think I'm going to -- I'm not going to offer any opinions, necessarily. But those are facts.

Q. Well, I'll tell you that Janssen

Page 529

strongly disagrees that those are facts, that everything you say are facts, and so to the extent you intend to testify to those, I need to know.

When we allocated time and when we asked for time, there was nothing mentioned about Noramco in the report. I didn't come here prepared to ask you questions about Noramco. Noramco is separately represented in the MDL, and counsel for Noramco isn't even here, since you didn't offer opinions about Noramco.

So I need to know what you're intending to say about Noramco at trial, so when I go back to the judge or the special master and ask to either have those opinions stricken or for additional time to depose you, we understand what that testimony and opinions is going to look like from your perspective.

MR. RAFFERTY: I'm going to object to the lengthy lecture to the witness, all right. Just ask your questions and he'll answer them.

A. So I don't have any specific

Page 530

opinions on Nor -- I mean, on this, but these are facts that I'm certainly happy to address if I'm asked by plaintiffs or defendants, and these facts are well laid out in the reliance materials.

MS. FREIWALD: As counsel for Purdue, I just want to join in that objection to the extent what you're saying implicates opinions that are nowhere in your report related to Purdue.

THE WITNESS: That's an objection.

Q. You're not intending to testify at trial as a fact witness; you're intending to testify as an expert witness, correct?

A. That's my intent, right. That's the way I see it. I do recognize, and I leave this to counsel, and I do this somewhat cautiously -- I don't want to get into -- I mean, the fact is that I was at the agency in '93 and '94, for example, and I did take certain actions on one of your products.

So I do have firsthand knowledge. I leave it to you and counsel here and the

Page 531

Court.

I was retained as an expert witness, and I certainly have been cleared by, as I understand it, by DOJ to testify fully, but I leave it to the Court -- I mean, understand that -- I mean, I leave it to you to characterize me, and I think the best characterization is an expert, but I do want to fully disclose that I am a -- that I do have firsthand knowledge.

COUNSEL: Objection.

A. I'm sorry, I just want to disclose that I was there. So I just want to make sure that's not in --

MR. RAFFERTY: In the interest of time, I'll be happy to discuss with you what our position is on this on the first break.

MS. LAURENDEAU: About Noramco?

MR. RAFFERTY: Yes.

MS. LAURENDEAU: Okay. We'll come back to that, if necessary.

Q. You said you've been cleared by DOJ to testify fully. Is that regarding the work

Page 532

that you did on opioids while you were at FDA?

A. I have -- I have -- my understanding is that I have no restrictions on me in testifying at trial about opioids on any of the subject matter in this litigation. That's my understanding.

Q. Has FDA, to your understanding, waived its privilege with respect to the deliberative process pertaining to opioids in connection with your testimony?

A. I would not want to speak for FDA.

Q. Has FDA told you that it's waived its privilege with respect to your testimony?

A. I do not want to speak for FDA. Those kind of questions -- I've not had any discussions with regard to privilege. I simply asked -- informed HHS, FDA, and DOJ that I was testifying, and I asked in essence whether there was any limitations.

Q. And I think you said yesterday, you're not intending to speak or offer opinions on behalf of FDA; to the extent you're testifying or offering opinions here, they're your own personal views and opinions, correct?

Page 533

A. Exactly. Now -- that's exactly correct. If you ask me a question that's factually of what was FDA's view in 1994, you know, I can answer that. I'm speaking for me. I guess I'm speaking for me as former Commissioner. But I may have knowledge of what I said in 1994 as FDA Commissioner.
Q. Your report cites and quotes several of Janssen's internal company documents as well, doesn't it?
A. Sure.
Q. And just as with some of the other defendants you've testified about earlier in your deposition, you're not intending to offer any opinions in talking about those documents, if you're permitted to do so, about Janssen's motivations, correct?
A. I -- of course not.
Q. You're also not intending to offer any opinions about Janssen's intentions or state of mind to the extent a corporation can have a state of mind, correct?
A. Of course not.
Q. And that includes any testimony you

Page 534

might give about information expressed in internal e-mails, business plans, or other Janssen company documents, correct?
A. Let me just see your question.
MR. RAFFERTY: Object to the form.
A. Can you restate the question a little?
Q. Sure. You're not intending to offer any state of mind or motivation opinions through your testimony about information expressed in Janssen's internal e-mails, business plans, or other company documents, correct?
A. Nothing about subjective intent.
Q. I'm going to ask you some questions about Duragesic, which I know from your prior testimony you have some familiarity with.
Duragesic's indicated for the management of chronic pain, correct?
A. Could you -- could we just -- can I trouble you for the label --
Q. Sure.
A. -- just so I have it so we can --
Q. Do you want the initial approval or

Page 535

do you want the current approval?
A. Well said. Whichever your question is going to refer to.
Q. Okay. Let's show you both then. Because it's -- you're not sure, as you sit here today, without looking at the Duragesic label whether it's indicated for the management of chronic pain?
A. Duragesic?
Q. Yes.
A. That was not what I indicated it for. When I was Commissioner, that certainly was not the indication in 1994.
Q. Okay.
A. But I just want -- I want to be precise, ma'am. It's not my memory of how -- what the intended use was.
MR. RAFFERTY: What number is that?
MS. LAURENDEAU: This is Exhibit 19.
(Reporter interruption.)
(Exhibit Kessler-19 marked for identification and attached to the transcript.)

Page 536

BY MS. LAURENDEAU:
Q. So Dr. Kessler, if you look under the indications and usage for the --
MS. LAURENDEAU: Can we turn this on, please.
A. Can we just -- can you just help me make sure we agree, this label -- just let me look to the last page, if I can, and see what the date is. Or actually it's sometimes up here.
Q. In the bottom right-hand corner it says, Revised September 2018.
A. Correct. Thank you.
Q. Okay.
A. Thank you very much, ma'am.
Q. If you look in the indications and usage, it says, Duragesic is indicated for the management of pain in opioid-tolerant patients severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.
Is that correct?
A. That is correct. Not what you

Page 537

asked me prior. That -- your prior question was incorrect. And there lies the rub.
Q. Okay. So you wouldn't describe this as being indicated for the management of chronic pain?
A. Absolutely not.
Q. Okay. Under dosage and administration --
A. That's not what that -- that's not what the indication is for.
Q. Okay. Under dosage and administration, it states, To be prescribed only by healthcare providers knowledgeable in use of potent opioids for management of chronic pain. Correct?
A. That's what dosage and administration says.
Q. Okay. Do you have your report in front of you, Dr. Kessler?
A. I do, ma'am.
Q. Can you look at paragraph 280 of your report, please.
A. Paragraph 280?
Q. Correct.

Page 538

THE WITNESS: Gerard, can I get -- is Gerard there? Can I just get -- if there's a document -- no, there's no documents, so hold it.
Q. There's no document; it's just an opinion.
A. Yes.
Q. You state in paragraph 280 of your report, Spurred by Janssen's marketing, use of Duragesic --
A. Just let me get to the actual portion of the paragraph. Spurred by Janssen's marketing -- yes.
Q. Use of Duragesic did spread beyond the post-operative period and the healthy cancer patient.
A. Yes.
Q. That's your opinion?
A. Oh, no question about that.
Q. Okay. And you believe that expanded use of Duragesic shouldn't have happened, right?
A. That expanded use to chronic back pain and osteoarthritis beyond those was

Page 539

off-label unless it -- unless there were no alternative options -- whether alternative options were tried first.
The problem is, it expanded to those indications without the requirement that other options be tried first.
Q. Okay. So my question was a little bit different. You believe that the expansion of Duragesic beyond the post-operative period and the healthy cancer patient should not have occurred, correct?
A. I believe that that's correct, and it shouldn't -- because when you look at what the expansion was, that expansion was not limited to those cases where this -- where the alternative treatments were inadequate. So the expansion into those conditions without that caveat made much of Duragesic's prescribing off-label.
Q. And so it's your opinion that some expansion beyond the post-operative period and the healthy cancer patient was okay, but the expansion that occurred was too great. Is that correct?

Page 540

A. I think generally that is -- it's a pretty general statement. I think to be specific, that no one should have been prescribed Duragesic -- if I had any idea that it was being expanded the way it was expanded, I would have -- after I did the label, that was off-label I think is the way I would say it.
Q. You believe the expanded use of Duragesic spurred by Janssen's marketing made overdoses and abuse more likely, correct?
A. Absolutely. No question in my mind.
Q. And the expanded use beyond the post-operative period and the healthy cancer patient made overdose and abuse more likely, correct?
A. Sure. The more prescription -- the more promotion, certainly promotion off-label, certainly promotion off-label when other alternatives were not tried, were not required to be tried, that put more drug in interstate commerce, and we know that leads to more abuse.
Q. It's within doctors' rights to prescribe any medicines off-label, correct?

Page 541

A. A doctor in his or her judgment may do off-label. I wouldn't want to just say it's in doctors' rights. Certainly under FDA law, that's correct. There are other implications.

Doctors are free, subject to other limitations and standards of care, to do things off-label. That's always been the case.

Q. FDA certainly doesn't limit doctors from prescribing medicines off-label, correct?

A. Generally, that's correct. There's certain restricted distribution drugs, but, you know -- and I think -- but those would be rare, I think.

Q. FDA has never restricted doctors from prescribing opioids off-label, has it?

A. Oh, I certainly did in Oralet.

Q. Okay. Other than Oralet, has FDA ever done anything to restrict doctors from prescribing opioids off-label?

A. The Oralet is the one that comes to my mind.

Q. And given that you did it in Oralet, that's something that FDA can do if it deems it necessary, correct?

Page 542

A. There's something called restricted distribution when compounds are, in essence, ultra-hazardous.

Q. Is that something you as Commissioner of FDA did to restrict the off-label use of Oralet, correct?

A. Yes.

Q. That's not something, to your knowledge, that FDA has done with respect to any other opioid products, correct?

A. I don't, sitting here, recall. I'd have to -- I don't recall, sitting here. I don't know the answer to that question. I'd have to do a little more research.

Q. FDA certainly hasn't placed any restrictions on doctors' prescribing of Duragesic off-label, correct?

A. I think that -- I think that would be a true statement. I think FDA did, certainly in my statements -- let me just fix my microphone.

I wouldn't characterize my statements as restrictions on doctors. There may be a word -- what's a better word than

Page 543

restrictions -- certain caveats to doctors, I think, would be a fair way to characterize what we said back in 1994.

Q. You may have given doctors advice or warnings or precautions about prescribing Duragesic, but you never placed any prescriptions -- or any restrictions on doctors' ability to prescribe Duragesic off-label, correct?

A. That's correct, ma'am.

Q. You also never -- to your knowledge, FDA has never placed any restrictions on doctors' ability to prescribe Nucynta off-label; is that correct?

A. That's correct.

Q. FDA knew, prior to approval of Duragesic, that it would potentially be prescribed by doctors off-label, correct?

MR. RAFFERTY: Object to the form.

A. You want to give me the original label so -- I want to make sure -- I wasn't there on the approval of Duragesic, and you're asking me what FDA knew. So I just want to look at the original label if you can give me

Page 544

that.

Q. I'll come back to it. That's okay. I have another document I'll show you on that in a bit.

Duragesic's approved indication has never been limited to cancer pain, correct?

A. The way you phrase it, I think we discussed this yesterday, that's not the phrasing of the indications. The indications are as set out in Exhibit 19. But we certainly were on record with the manufacturer and with the public that we thought that there may be a few instances beyond that.

But the understanding -- certainly my understanding was that it was primarily cancer. But I did not want to restrict it, as you said, just to cancer pain. But that was not a wholesale opening.

Q. The approved indication was never limited to cancer pain, correct?

A. The approved indication is exactly what it says.

Q. And the approved indication does not say and has never said that it's limited to

Page 545

cancer pain, correct?
A. Correct. But you also have -- you know, you have FDA statements about interpreting where this should be used.
Q. I understand that. I'm asking about the approved indication.
The Duragesic approved indication has never stated that it's limited to cancer pain, correct?
A. I answered that question.
Q. I'd like you to answer it again, because I don't think you directly answered the question.
A. Yes. I mean, the words of the indication are exactly the words of the indication. And it's not phrased in those terms. The indication is phrased differently.
Q. Do you think the words of the indication communicate in different words that the indication is limited to cancer pain?
A. I think the words of the indication -- I don't think the indication would preclude all non-cancer pain from any forms of non-cancer pain being used. So no, I

Page 546

think there are some forms of non-cancer pain that the label would allow, but they would have to meet all the requirements of the indication.
Q. Is the word "cancer" anywhere -- is it anywhere in the indication for Duragesic, to your knowledge?
A. No, it is not.
Q. And the FDA could have limited Duragesic's indication to cancer pain, couldn't it have?
A. I had -- I made that decision, ma'am, and I made a decision that, as I think I said yesterday, that it was -- it should be used primarily for cancer pain, but we didn't want to restrict it because we saw there may be some other patients that may fit that definition. That's exactly what I said and was communicated publicly.
Q. Just to make sure I understand, you specifically made the decision not to limit Duragesic's indication to cancer pain; is that correct?
A. Let me get exactly what decision I made so the record is clear.

Page 547

Q. Could you note for the record what you're looking at or reading from?
A. I'm reading a 1994 document from my associate, Dennis Strickland.
Q. Would you mind if we attach that to the --
A. You can put a sticker --
Q. -- to the deposition transcript? You can go ahead and read to it, but I'd like to mark it and then take a look at it on a break.
(Exhibit Kessler-20 marked for identification and attached to the transcript.)
BY MS. LAURENDEAU:
Q. You're reading from Exhibit 20 now, Dr. Kessler?
A. I am, ma'am. So this talks about the original label, but I mean, I'm reading the fourth paragraph, and halfway down, it says, Consideration was given to limiting the approved indication for the product to the treatment of pain of malignancy, i.e., cancer pain, but it was known that there is a small

Page 548

fraction of chronic pain patients with pain of non-malignant origin who can also potentially benefit from the product.
That was a statement that was made after my discussions on the compound.
Q. And that was your decision?
A. I wouldn't want to say -- I tended not -- I tended to be a pretty consensus-oriented guy at the agency. I think others would probably look at it and say it was my decision.
But I can tell you it was -- it was certainly done with the CDER. I would never want to overrule CDER unless I -- there may be rare instances. I think this was a fair read of a consensus of us, but I -- I think I had a little more voting power maybe. But that's what the record shows.
Q. You certainly were involved in and agreed with and even had maybe a little more voting power than anyone else with respect to that decision, correct?
A. I stand by that decision, yes. I think that -- I still think that is probably in

Page 549

this complex world of, you know, strong opioids, others may differ. I think that that -- I mean, I'm always a little reluctant 25 years later, right, I think that's still -- those words probably still would be my opinion today.

Q. So if I understand your testimony, you do not regret that decision, correct?

A. Oh, I certainly regret that decision. I certainly regret that decision.

Q. But you stand by it. You think you made the best decision at the time, correct?

A. Yeah. If I had any knowledge of your company's several years later marketing for back pain and osteoarthritis, and being in a competitive war with Purdue over this product, I would -- I would certainly have done something differently. I just didn't know that.

Q. We talked a bit yesterday about, in 2013, the FDA rejected an advisory organization PROP's request to make a distinction between cancer and non-cancer pain in opioid labeling. Do you recall that?

Page 550

A. I remember we discuss PROP. I apologize, I don't remember that specific aspect of discussing it yesterday.

Q. Okay. Do you recall that in 2013, the FDA specifically declined -- specifically declined a request to make a distinction between cancer and non-cancer pain in opioid labeling?

A. Yeah. I mean --

THE WITNESS: Gerard, can you just hand me my general -- sorry, I want to have PROP in front of me, ma'am.

Q. I'm just going to move on, because I don't think we have time to get into it.

A. Okay. That's fine, but I'm happy -- I just want to pull it up so I can know exactly what the PROP said.

Q. Okay.

A. But I think that -- I --

THE WITNESS: Never mind, Gerard.

Q. Duragesic has never been indicated for post-operative pain, has it?

A. That's not what the indication says, correct.

Page 551

(Exhibit Kessler-21 marked for identification and attached to the transcript.)

BY MS. LAURENDEAU:

Q. I'm going to show you the original approval for Duragesic. You just confirmed by looking at Exhibit 19 that Duragesic currently isn't indicated for post-operative pain, correct?

A. That's -- I'm sorry. That's not what the indication says, correct, in those terms. It's just the same thing as saying it's indicated for chronic pain.

Q. Well, it currently says -- let's take a look at the contraindications in Exhibit 19 for the current Duragesic label. Do you have that in front of you?

A. Yes.

Q. It currently says --

MS. LAURENDEAU: Can we turn this on, please.

Q. Under contraindications -- which means Duragesic is not to be used in these circumstances, correct?

Page 552

A. Exactly, ma'am.

Q. Acute or intermittent pain, post-operative pain, mild pain. Correct?

A. Correct, that's exactly what it says.

Q. So it's currently contraindicated in post-operative pain, correct?

A. That's exactly what that said. You asked me what the indications were. But you're exactly correct.

Q. Okay. And let's look at what I've marked as Exhibit 21.

A. Thank you.

Q. Which, if you look on the last page, you'll see it's the Duragesic label from August of 1990.

A. Thank you very much, ma'am.

Q. Under indications and uses, it says, Duragesic --

A. I'm sorry, what page are on?

Q. We are on --

A. These old labels, unfortunately the indications are in the wrong place.

Q. It's the actual --

Page 553

A. I don't mean the wrong place, but FDA didn't get it right. Indications -- it's sort of bizarre that they're in the middle of the --
Q. It's on the actual third page --
A. Thanks --
Q. -- not counting the pages on the back.
A. Thanks an awful lot, again.
Q. Do you see indications and usage now?
A. I do, yeah.
Q. In the second paragraph, indications and usage, Duragesic is not recommended in the management of post-operative pain, correct?
A. Correct.
Q. So is it your understanding that Duragesic has never been indicated or approved for post-operative pain?
A. Yeah. It's a little more complicated than that.
Q. Do you think it was ever indicated or approved for post-operative pain?

Page 554

A. I think that what you read me, again, is, it says, Duragesic is not recommended in the management of post-operative pain. The prior sentence says what it's indicated for.
If you changed your question to say, was Duragesic ever recommended for post-operative pain, I would say no.
Q. Would it have been -- would it have ever been appropriate, in your opinion, for Janssen to market Duragesic for acute post-operative pain?
A. No, because we know that that doesn't meet -- it has to meet the indication statement.
Q. Would it have ever been appropriate for Janssen to market Duragesic for use in the post-operative period?
A. I want to think about whether there's ever a case for that. I just would want to think about that a little.
Q. In January of 1994, I think we talked a bit about the indication in Duragesic's label being updated. Do you recall

Page 555

that?
A. Yes.
Q. That's the label update that you were personally involved with, correct?
A. At that time, yes. I think that's what the record shows and I -- yes.
Q. You were -- at the time of the 1994 Duragesic label change, you were Commissioner of the FDA, correct?
A. Exactly.
Q. You were personally involved in the updated label for Duragesic, correct?
A. Yes.
Q. That was an important issue for you, as Commissioner, to be personally involved with, correct?
A. The issue arose out of a tragedy. So that was what was -- so I think the fair answer to your question would be yes.
Q. What was the reason for the label change?
A. Misuse.
Q. What type of misuse?
A. Death.

Page 556

Q. Was it -- can you explain any more about the circumstances? Do you recall?
A. My recollection -- and again, some of this is refreshed based on the record. My -- my recollection was that someone brought to my attention -- I don't know whether someone in the Commissioner's office brought to my attention or I saw firsthand that there was a young man in Florida who had received Duragesic after dental pain, and there were some issues on -- there were some issues with regard to temperature or a heating pad on Duragesic, and he died.
And his mother didn't want that death to, I think, go without -- to be in vain. She wanted other people not to incur that same.
So I became aware of that, and obviously, as the record shows -- as Exhibit 20 shows, I met on that issue, and that issue led to a broader examination of Duragesic at that time.
(Exhibit Kessler-22 marked for identification and attached to the transcript.)

Page 557

BY MS. LAURENDEAU:
Q. Okay. I'm going to show you what I've marked as Exhibit 22. Exhibit 22 is an Associated Press article from January 18th, 1994 entitled, FDA Says Some Doctors Dangerously Misusing Potent Painkiller.
A. Just a second. Show me exactly where you're quoting from.
Q. I'm just reading the title of the article.
A. Thank you.
Right, that's the title.
Q. And if you look at the fourth paragraph of the article, you're quoted in this article, correct, or you --
A. That's me.
Q. An interview you gave is quoted in this article?
A. Right.
Q. And the quote is, We are seeing an emerging pattern of misuse, FDA Commissioner David Kessler said in an interview.
Did I read that correctly?
A. You read that exactly correctly.

Page 558

Q. Do you recall believing, as of January 1994, that you were seeing an emerging pattern of misuse with respect to Duragesic?
A. My memory is a little fuzzy, but certainly, that is consistent with my memory. I don't -- I mean, I think that -- I mean, I would urge between this letter and the minutes and the letters to Connie Mack. I think they reflect what we knew or saw at the time. I'm not sure I have a lot of memory other than what's in the record.
Q. And you certainly don't dispute, as you sit here today, that as of January 1994, FDA was aware of an emerging pattern of misuse with Duragesic, correct?
A. No, because obviously, this was used in dental pain, and it was not -- you know, we went through that that was misuse, didn't think it should be used in dental pain.
I guess we saw four other deaths, right, one in chronic back pain, one in wisdom teeth, one in sickle cell, and one after a nine-year-old with a tonsillectomy. So that certainly didn't meet the indications as we saw

Page 559

it.
Q. These were all situations in which you believed Duragesic was not indicated for use, correct?
A. Yeah. I want to be a little careful. I think we found four deaths. I don't have a record exactly on the prescribing history of those or -- for example, on the sickle cell death, for example.
I think generally, I would agree with your -- I would say yes to that. But again, the record is a little limited on these cases.
Q. Okay. You thought the upgraded warning for Duragesic in 1994 was sufficient to warn doctors of the risks of Duragesic, correct?
A. I wouldn't agree with the way you framed your question. I didn't know that it was sufficient -- I mean, I did the best I could, based on what I knew at the time with my colleagues. Clearly, it wasn't sufficient for marketing practices later on.
Q. Based on the FDA's information it

Page 560

had, which we know included an emerging pattern of misuse and use in unapproved indications, you did the best you could, and the best -- what you thought was appropriate at the time was to upgrade and increase the warnings for Duragesic in 1994, correct?
A. I think that's fair.
Q. You were Commissioner of FDA for another three years after the Duragesic label change in 1994, correct?
A. Approximately.
Q. And this remained an important issue for FDA after January of 1994, correct?
A. Sure. I mean, every drug and every issue of misuse is important.
I will tell you that -- I mean, there are other issues after this that occupied my time. I have no recollection of other interaction on this issue after this.
Q. Well, one of the other things you're quoted as saying in this AP article is, quote, This is one of the more striking examples of where we really need to make sure a medicine is being appropriately used.

Page 561

Did I read that correctly?
A. That's exactly what I said.
Q. Okay. And you believed that to be true as of January 1994, correct?
A. Sure. Whenever there's a needless death, I took that very seriously.
Q. What steps did you personally take between January of 1994 and February of 1997 when you stepped down as Commissioner to ensure that Duragesic was being appropriately used?
A. I don't have any recollection, sitting here, of firsthand knowledge. You have to look at the record to answer that question. Obviously, there was the label change. There was the "Dear Doctor." That's what I was involved in. And obviously, the public education. That's what I was involved in.
Q. Nothing happened during the remainder of your tenure at FDA that you recall requiring your personal attention on Duragesic; is that correct?
A. Correct, ma'am.
Q. You certainly expected that the employees working under you at FDA would

Page 562

continue to closely monitor whether Duragesic was being appropriately used, though, correct?
A. Sure. But I think the word "we" here -- I think you're overstating it a little. The "we" I think is a collective "we" in that sentence. I would have expected the company; I would have expected doctors. I mean, I was -- that "we" is to make sure medicine is being appropriately used, that was as strong a signal as I could give. It's a pretty strong signal. Maybe I could have given a stronger signal to a company and to the world.
So I don't think it's just FDA, but I think it's a fair point that those instructions were -- that was an important statement.
Q. When you said, We really need to make sure Duragesic is being appropriately used, you meant to include FDA as well as other stakeholders, correct?
A. I think everybody would be included in that. I think the pharmaceutical company obviously has primary responsibility to make sure, certainly to the extent -- to the extent

Page 563

that it's controlling its promotion, yes.
Q. Okay. I'd like to direct your attention --
A. May I give these to the court reporter?
Q. Sure, please.
A. Thank you very much.
MR. RAFFERTY: You need to give yours as well, just the letter.
THE WITNESS: I'm going to give this -- I'm giving over my documents. That's fine.
Q. If you keep it in the yellow, we'll remember that it's yours and make sure you get a copy back.
A. I get it back. Thank you very much, ma'am.
Q. I'd like to direct your attention to your report starting on paragraph 273.
A. Paragraph 273.
Q. Yes. And this is where you're talking about Dr. Curtis Wright's --
THE WITNESS: Can I trouble you, Gerard, for that paragraph, please.

Page 564

Q. So this is where you're talking about Dr. Curtis Wright's medical officer review of the NDA for Duragesic, correct?
A. Correct.
Q. You note that even before reviewing the NDA for Duragesic, Dr. Wright raised concerns with Janssen about diversion of the product, correct?
A. That's exactly what I say. But let me just go to the document.
Q. I just want to know what you say in your report. I don't need you to confirm with the document right now.
A. Okay. Then the report says what it says.
Q. Okay. And that's your -- based on your review of the document, that's how you summarized it, correct?
A. That's exactly what the report -- hold on a second. Let me just -- yes, that's exactly what the report says.
Q. And that's your report that you prepared, correct?
A. Yes, absolutely.

Page 565

Q. Okay. And so in this medical officer review of the NDA, Dr. Wright --
THE WITNESS: Parvin, or somebody, can you just find me this medical officer review, please.
A. I'm sorry. I apologize, ma'am.
Q. And moving on in that paragraph 273, Dr. Wright, at a pre-approval meeting with Janssen, also asked about the potential for extraction of fentanyl from used or unused system and suggested ways to reduce the abuse potential, including incorporation of naloxone.
A. Perfect.
Q. So even prior to approval, Dr. Wright at FDA was also talking about abuse potential for Duragesic, correct?
A. He was.
Q. And in paragraph 275, you note that Dr. Wright noted that once clinicians learned that the system can provide continuous opioid analgesia through the night, the system will be used in a much broader clinical population than intended, correct?

Page 566

A. I'm sorry. I was just looking -- I'm there, yes. I'm exactly there.
Q. That's what you state in your report, correct?
MR. RAFFERTY: I'm going to object to the form. I don't think that was exactly quoted correctly.
A. The quote, as I read it, It is the opinion of the reviewer that once the clinicians learn the TTS fentanyl system can provide continuous opioid analgesia through the night, that the system will be used in a broader clinical population than intended.
Q. That's something you quote Dr. Wright as noting in his medical officer review, correct?
A. I do that.
Q. And that indicates that Dr. Wright understood there was a likelihood that Duragesic would be used off-label at some point, correct?
A. Oh, no. I mean, again -- there's off-label, and there's off-label, okay.
Q. What's the difference between

Page 567

off-label and off-label?
A. Oh, there's the off-label that may happen from the anesthesiologist. And Curtis is an ER doc. He's a toxicologist. There's a world of difference between the -- there's a world of difference between the anesthesiologist going in the cabinet and using a product inappropriately, as we know that occupational hazard is, and that's off-label, or a doctor, in his or her judgment, making a decision and promotional campaigns to market it broadly for chronic back pain and osteoarthritis.
So there's -- I mean, there's the one-offs off-label, which I -- and then there's the campaigns that are used broadly.
So I guess the answer to your question is -- what I meant was the extent.
Q. Okay. But Dr. Wright at least knew that there would potentially be some off-label use in what he says a much broader clinical population than intended, correct?
A. That's exactly what Curtis said.
Q. And Dr. Wright also says, if you

Page 568

look at --
A. He put the company on notice, is a fair way to say it.
Q. Okay. And he was on notice, correct?
A. Sure. I mean, his knowledge put him -- I don't know what that means.
Q. Well, he knew it was a potential risk, correct?
A. That, I would agree with.
Q. FDA was on notice, correct?
A. FDA -- Curtis had knowledge, I think is the way to say it best.
Q. Curtis worked for FDA, correct?
A. Yes.
Q. He was the medical officer charged with reviewing the NDA for Duragesic, correct?
A. Right.
Q. And do you dispute that if Curtis knew something and included it in his medical officer review, that that's something that FDA knew?
MR. RAFFERTY: Object to the form.
A. I mean, I clearly say Curtis knew

Page 569

this. There's no question, ma'am, that Curtis knew this.
Q. And you agree FDA knew it, correct?
A. That's a metaphysical question, almost Wittgensteinian in nature. I will certainly -- it's -- for example, just because we're in Washington, when we say the White House knew, who knows what? You've got to be careful on those statements. That's my only issue.
I certainly am not taking any issue with the fact that Curtis knew this. In fact, he said to your company he knew this before he even opened the application because he was sensitized to this because he knew the very strong potency of the product.
Q. Are you familiar with Janssen's efforts to monitor for abuse, misuse, or diversion of Duragesic?
A. I have some familiarity with that. I believe I've seen some documents to that effect.
Q. Did you review the deposition testimony of either Gary Vorsanger or Bruce

Page 570

Moskovitz regarding the abuse, misuse or diversion of the efforts to monitor the abuse, misuse or diversion of Duragesic?
MR. RAFFERTY: Object to the form.
A. I spent more time with Vorsanger, I believe, but I searched both. But Vorsanger I cite in a deposition, and I believe I've spent more time with that, yes.
Q. Did you evaluate the risk management plan that was implemented for Duragesic in June 2007 years before the class-wide REMS for extended release opioids went into effect?
A. If you can -- can you just give me that risk map so I can just reflect -- refresh my memory on that risk map?
Q. I don't have it in front of me.
Do you remember if you reviewed it, as you sit here today?
A. I'd have to go back and check. I mean, that specific one, I just have to go back and check, ma'am.
Q. Are you aware that Janssen had a risk management plan in place for Duragesic

Page 571

years before the class-wide REMS for extended release opioids went into effect?
A. That was not uncommon for a number of those compounds.
Q. And you knew that Duragesic had a risk management plan implemented years before the class-wide REMS went into effect, correct?
A. Yes, I believe that's correct.
Q. Did you know, pursuant to the Duragesic risk management plan, that Janssen regularly provided FDA with progress reports?
A. That was a part of the risk management -- those are part of the risk management requirements.
THE WITNESS: Can I just have the -- pull the risk map if I'm being asked about it.
Q. I have very limited time, so I'm just asking what you remember as you sit here today, and you can tell me if you think you need to review it to answer, and that's fine, but I don't have time for you to look at them.
A. I just want to be precise exactly.
But I am familiar with progress

Page 572

reports, and I have seen progress reports.
Q. Okay. Great.
And do you recall that the progress reports generally looked for safety signals or new safety signals with respect to misuse, abuse or diversion of Duragesic?
A. I think there were sections on that, but I want to review before I give you any opinion on that section of the risk map.
Q. In forming your opinions in this case, what, if anything, did you do to measure the rate of abuse, misuse or diversion of Duragesic?
A. I don't -- I did not do any specific analysis on that question.
Q. Are you relying on any analysis by any of the experts in this litigation?
A. I'm not relying on any other experts, but the quantitative aspects of -- there are some -- I do have documents that talk about that and the extent of the abuse.
I am familiar firsthand with instances of abuse and cases of abuse, but I have not done any specific quantitative

Page 573

analysis of that.
And I'm issuing no opinion quantitatively on the specific rate of abuse.
Q. Did you review Janssen's cumulative review of iatrogenic addiction associated with the use of the transdermal Duragesic fentanyl patch?
A. You'd have to refresh my memory on that document.
Q. Okay. I'm going to show it to you.
(Exhibit Kessler-23 marked for identification and attached to the transcript.)
BY MS. LAURENDEAU:
Q. I'll hand you what I've marked as Exhibit 23. Exhibit 23 is a document entitled, Cumulative Review of Iatrogenic Addiction Associated With the Use of Transdermal Duragesic Fentanyl Patch. And it's dated September 8th, 2006.
Is this a document you recall reviewing in connection with forming your opinions, Dr. Kessler?
A. At the top of my mind, I don't have

Page 574

any -- I'd have to look at the document. I'm drawing a blank on this specific one. I may have. I've got to go take a look. I think it's on -- I'm pretty sure it's on my reliance list, but I'd have to go back and check.
Q. Okay. I will represent to you that I did not see it on your reliance list. Would you mind checking on a break and letting me know if you see it or if you think I missed it?
A. Yeah. Let me check my -- I have it on my hard drives, and I have much of -- I have much of the submissions to FDA. And the question is, is it in any of those FDA submissions. So I just don't know -- I'd be happy to check and see whether it was part of any of the FDA submissions that are on my reliance list.
Q. I'm going to have you look at page 9 very quickly, and show you that page 9 evaluated fentanyl patch's exposure from launch to June of 2005.
A. I'm sorry. Just show me where you're reading, please.
Q. Table 1.

Page 575

A. Table 1.
Q. Fentanyl patch's exposure from launch to June of 2005.
A. Right.
Q. And the total patient days is over 1.6 billion, correct?
A. That's what that says.
Q. And if you look at the results, the results say, the search of scepter [ph] retrieved a total of 117 cases, with a preferred term of dependence, 14 cases, or drug dependence, 103 cases.
Do you see that?
A. That's what that says, yes.
Q. If the results of this cumulative review of iatrogenic addiction showed a total of 117 cases combined of dependence and drug dependence in more than 1.6 billion patient years, would you agree with me that that's a low rate of dependence?
A. Yeah, but --
MR. WEINBERGER: Patient days, not patient years.
MS. LAURENDEAU: Patient days. Let

Page 576

me restate the question.
Q. Would you agree with me that if this report shows a total of 117 cases of dependence in more than 1.6 billion patient days, that that's a low rate of dependence?
A. Your question says, if the report. The report says there are 117 cases out of the 1.6 billion. And I would agree with you that that would be a low number.
But I think everybody would agree that on these reporting systems, these are woefully inadequate and pick up only a fraction, if that, of the total number of cases. They're not that -- these kind of studies are not -- we have this problem with adverse event reporting all the time.
So, you know, I would agree with you based on these numbers in this report, as you said, that that would be, you know -- that would come out to the number. But don't hold your breath that the 117 is accurate. I'm sorry.
The best way to say it is, the 117 is clearly significant underreporting.

Page 577

Q. So even if the actual cases were ten times what was reported, it would still be a low rate of dependence based on the patient days of exposure, correct?
A. If that was the number that you hypothesized to use, I would agree with you that that would be low.
Q. And you don't know what the actual rate was, but the iatrogenic addiction cumulative review is something that companies and FDA rely on to get a sense of what the actual rate of an adverse event, in this case, dependence, actually is, correct?
MR. RAFFERTY: Object to the form.
A. No. I think that what you would want to do more accurately is to take a defined cohort of people -- a defined cohort -- and there are studies like this. And you would want to take a cohort that has the number of people who became addicted from prescriptions, and you'd want to be able to understand what they were treated with.
So I wouldn't -- this is hypothesis generating, as they say in the trade. This

Page 578

isn't really scientific evidence. There are a whole host of studies that I'm willing to give you on iatrogenic addiction. I mean, again, this is -- I mean, this is what it is.
Q. And this is something that FDA actually asked Janssen to do, correct?
A. Sure. I mean, this is -- FDA has asked for a whole host of things. This is sort of an epi study. But there are a whole host of studies that are being done that I would say are scientifically -- they'd have a scientific -- they have a more rigorous scientific basis than just simply a signal detection.
Q. You said that the actual rate is clearly higher than this. What is the actual rate?
A. I don't know. I can tell you that -- I can go through studies about the iatrogenic addiction rate.
I think I testified yesterday that if one looked at opioids in general, I was comfortable with about -- you know, from clinical experience, with about 20 percent.

Page 579

But again, I'm happy to go through the literature and show you the range within that literature.
MS. LAURENDEAU: Okay. Let's take a quick break.
MR. RAFFERTY: Okay.
VIDEO OPERATOR: 11:27, we are off the video record.
(Recess from 11:27 a.m. until 11:43 a.m.)
VIDEO OPERATOR: 11:43, we are on the video record.
BY MS. LAURENDEAU:
Q. Dr. Kessler, can you please turn to paragraph 265 of your report.
A. Yes, ma'am.
Q. In this opinion, you state that, Janssen contributed to the change in the practice of medicine with regards to pain treatment and the concomitant expansion of both the use and abuse of opioids by misleading promotion and marketing that minimized the risks and overstated the benefits of its opioid drugs.

Page 580

Did I read that correctly?
A. You did, ma'am.
Q. That's the opinion -- one of the opinions you intend to offer at trial in this case?
A. Yes, that would be fair.
Q. As I read your report, in this opinion, you're really talking about Duragesic and not Nucynta. Correct?
MR. RAFFERTY: Object to the form.
A. No.
Q. You're talking about both Duragesic and Nucynta?
A. I think the majority of the comments, to be fair, relate to Duragesic, but there are certainly issues with regard to Nucynta. But I would agree with you that Duragesic has a significant role in the formulation of that opinion.
Q. Is it your opinion that Janssen contributed to the change in the practice of medicine with regards to pain treatment and the concomitant expansion of both the use and abuse of opioids by misleading promotion and

Page 581

marketing of Nucynta that minimized the risks and overstated the benefits of its opioid drugs?
A. Yeah, I think that would be fair.
Q. Okay. I thought you testified yesterday that the change in the practice of medicine had already occurred at some point in time well before Nucynta was approved.
Did I mishear you?
MR. RAFFERTY: Object to the form.
A. Maybe yes and no. I think what -- I think what I said and, hopefully, is reflected in this report -- that activity in the early 2000s, late 1990s set the stage, but I believe that was continued throughout and even after, to the point where --
So maybe the question is -- you know, when I use the word "change," maybe I'm not as artful as I should be, but it's the change and that continued change in that perception.
So I think that there's an adding on or a perpetuation of that change. Maybe a more artful -- the change and -- perpetuation,

Page 582

not change, may be a more artful way of saying it.
Q. So you believe that after Nucynta ER was approved in 2011, the practice of medicine with regards to pain treatment changed as a result of some type of misleading promotion or marketing of Nucynta?
MR. RAFFERTY: Object to the form.
A. I think it contributed to the overall perception of how opioids was used, and I think that perception was improper.
Q. That perception existed well before 2007 -- or 2011, correct?
MR. RAFFERTY: Object to the form.
A. Well, again, I think it's a question of degree, and I mean, it's a question of collectively, over, really, 20 years of that -- that change in perspective from, again, what we knew in 1980.
I think -- it's a perpetuation of that change continued, I think is, again, the best way to say it.
Q. So you think the practice of medicine with regards to pain treatment would

Page 583

be different than it is today if Nucynta had never been approved and marketed?
MR. RAFFERTY: Object to the form.
A. I think the -- I think the -- I'm not arguing on its marketing -- I'm sorry. I'm not arguing on its approval --
Q. But I'm just saying, assume it was never approved.
MR. RAFFERTY: Excuse me. He was answering your question.
Go ahead, Doctor.
A. I think the -- I think the collective -- I can't quantitate it, but I think the collective perception of opioids as having less abuse potential -- stating, you know, something -- less withdrawal, less GI effects -- I think those things -- and certainly less abuse potential, less withdrawal -- I think those -- that's -- that was a collective -- collectively affected that change in medicine.
Q. And you think the practice of medicine today would be different if Nucynta had not been marketed by Janssen in the ways

Page 584

you take issue with?
MR. RAFFERTY: Object to the form.
Q. That's your opinion?
MR. RAFFERTY: Asked and answered.
A. I think it was -- I think it was a cumulative thing.
Q. And you think the practice of medicine today with regards to pain management would be different if Janssen had not marketed Nucynta in the ways that you take issue with?
MR. RAFFERTY: Object to the form.
A. I think, again, it contributed to this notion of less abuse potential, less withdrawal for strong opioids. That's what I think.
Q. And you think the practice of medicine with regards to pain management would be different today if Janssen had not marketed Nucynta in the ways that you take issue with, correct?
MR. RAFFERTY: Object to the form.
A. Sure, sure, because people obviously thought they had something, the way your company -- your client, sorry -- marketed

Page 585

this: this had a different withdrawal; this had different tolerability; you could use opioids, but because you have norepinephrine reuptake implications, that you would have opioid sparing.

I think that adds to the collective -- the collective way pain was being treated, yes. That marketing -- that marketing has -- marketing by your company had an effect. We know that.

Q. I want to focus just on Janssen now and not any of the other manufacturers.

How would the practice of medicine be different today if Janssen had not marketed Duragesic and Nucynta in the ways you take issue with?

MR. RAFFERTY: Object to the form.

A. Oh, I think Janssen -- I think the -- I can show you, just in general.

Q. I don't want to know what it did; I want to know how the practice of medicine would be different today.

MR. RAFFERTY: Objection. He's answering your question.

Page 586

A. So I think the practice of medicine -- you go back, you know; you look at how opioids were used. Back in 1990s, chronic opioids -- I mean, extended-release opioids were not recommended.

1980, that drug of choice book that I showed yesterday, if you look at, for example, this picture, you know, is very different than this picture.

And what you see is this sense of -- this perception without data that there would be improved functionality, that this can be used in a broad range of indications such as back pain, in osteoarthritis, I don't think would have ever happened -- I'm sorry -- that would not happen to the extent it would happen but for -- but for marketing.

Q. Do you think anything other than manufacturers' misleading promotion and marketing of their opioid products contributed to the increase in opioid prescriptions during the time period you're talking about?

MR. RAFFERTY: Object to the form.

A. I think that the -- if you're

Page 587

asking me about the increase in prescriptions, I think it was the misleading promotion of manufacturers that contributed to the increase of promotion [sic].

Your company specifically had probably the most extensive and most sophisticated system that I've seen on measuring return on investment, measuring return on investment on coupons, on detailing, in Ohio, in Akron, in Cleveland East, in Cleveland West, right.

Q. Okay. I --

A. So there was no --

Q. I understand --

MR. RAFFERTY: Hang on. He can finish his question.

Q. I have limited time, and you're jumping --

A. Sure. I'm sorry. I'm sorry. I apologize.

Q. You're going astray.

MR. RAFFERTY: You asked --

Q. I'm sorry, but you are going astray.

Page 588

MR. RAFFERTY: You know, you did not --

A. Go ahead. I'm sorry.

MR. RAFFERTY: You asked him a very open-ended question. He can answer.

MS. LAURENDEAU: I asked him --

MR. RAFFERTY: Otherwise, you can withdraw the question.

MS. LAURENDEAU: -- if anything else contributed, and then he started talking about my client's marketing.

MR. RAFFERTY: Are you withdrawing the question?

MS. LAURENDEAU: No --

MR. RAFFERTY: Well, then he's going to finish his question.

MS. LAURENDEAU: -- I'm not withdrawing the question.

No, he's not.

MR. RAFFERTY: Yes, he is.

MS. LAURENDEAU: You can object to use of the question later if you want to.

MR. RAFFERTY: Move to strike

Page 589

the -- move to strike the question.
MS. LAURENDEAU: Okay, great.
MR. RAFFERTY: Who was ruling yesterday?
BY MS. LAURENDEAU:
Q. Did anything other than manufacturers' marketing of their opioid products contribute to the increase in prescriptions, or was that entirely due, in your opinion, to manufacturers' misleading promotion and marketing of their products?
MR. RAFFERTY: Object to the form.
A. I would never want to state that -- I think you used the word "anything." I think there are -- I think that the predominant, the vast, the gravamen, the impetus, the major force, the overwhelming force was the marketing.
I mean, I think -- I mean, I do recognize -- and I think I say in this report that I think there were some individual doctors prior to the marketing and promotion that had beliefs that they should be -- they should be used for chronic pain, but I think

Page 590

they were few, they were far between, they did not get traction.
You know, would they have -- would those have contributed to an increase? Maybe 0.00000001 percent.
So when you say "anything," I think there's always things we can talk about, but this was overwhelming. I mean, this is an --
Q. You're not --
A. This is an epidemic of prescriptions. Again, you asked me what -- if I'm understanding your question -- what resulted in the increase in prescriptions. The prescriptions were promotionally sensitive, and that's what drove these prescriptions.
Q. And you think it's the increase in prescriptions that contributed or caused the increased use and abuse of opioids, correct?
A. As Dr. Sackler said, the increase -- which I agree, and Curtis Wright has said -- the increased amount of drug in interstate commerce is going to -- put more drug in interstate commerce, you're going to have more abuse.

Page 591

Q. In your opinion, are there any other factors other than the increase in the amount of opioid products in interstate commerce that contributed to the expansion of the use and abuse of opioids?
A. Sure.
Q. What are those other factors?
A. Well, I think we talked about the fact -- I mean, I don't think it's a very big percentage, if you look at the studies, but I think the fact that -- for example, we know that there are bad doctors, there are pill mills, there is -- there are criminals affecting the system.
So sure, that's got to have some effect on the abuse other than the increase in the amount of products in interstate commerce that resulted from prescriptions.
Q. Have you done any analysis to attempt to determine the percentage responsibility of bad doctors, pill mills, or other bad actors for the increase in the use and abuse of opioids?
A. I don't have a specific analysis on

Page 592

that. I do have data -- I mean, you can see it -- and I've looked at specific -- some specific data on how many some -- you know, some of these high-volume docs who get prosecuted, but I have not done any analysis myself of what percentage I can attribute.
But my understanding from the data that I've seen, that it's relatively small.
Q. You don't intend to offer any opinions at trial on the appropriate allocation of responsibility between manufacturers' purported misleading promotion and marketing of their products versus bad doctors, pill mills, or bad actors for the use and abuse of opioids, correct?
MR. RAFFERTY: Object to the form.
A. Specific allocations, 22 percent, 5 percent, 0.2 percent? No, I would not, not at all.
But I think that there should be no mistake that my opinion is that marketing drove this epidemic and the increase of prescription drugs. But I don't have a specific quantitative number for that, no.

Page 593

Q. Your opinion assumes that doctors were actually mislead by -- your opinion in paragraph 265 of your report assumes that doctors were actually misled by Janssen's misleading marketing, correct?
A. Misled? Sure. I mean, I guess that's probably correct. I'm not sure -- doctors follow -- I mean, we know --
I just have a little problem with maybe the question "assumes that doctors were actually misled," "actually misled."
Q. Well, if they weren't misled by the promotion and marketing that minimized the risks and overstated the benefits of its opioid drugs, then that wouldn't be the cause, as you believe it is, for the expansion of the use and abuse of opioids, correct?
A. Yeah, I think that's well said. I would agree that -- if you're defining "misled" like that, I would agree that doctors were misled, because we do know -- and your company has -- knows exactly, in exquisite detail, the return on investment and the promotional sensitivity of virtually all its promotional

Page 594

activities and measured that exquisitely and with, you know, a great deal of sophistication.
And we knew those drove prescriptions, and we know those prescriptions -- I mean, a very significant number of those were done, in essence, off-label.
So that was -- I mean, because they didn't -- I mean, it could not be that there were no alternatives for this vast number of prescriptions.
Q. So your opinion assumes doctors were misled by Janssen's marketing that minimized the risks and overstated the benefits of Duragesic and Nucynta, correct?
A. I don't think it assumes anything. I think if you look at the record, if you look at the indication, it is -- the amount of prescribing for chronic back pain and osteoarthritis and the, in fact, back -- the marketing for those clearly shows that that was off-label because it did not have -- that did not include using alternatives showing that alternatives were inadequate.

Page 595

Q. Is it your opinion that every off-label prescription of Duragesic or Nucynta was a result of misleading promotion and marketing by Janssen?
A. No. I would never say that all. But just look at your ROI numbers, and you will see the extent and the -- in essence, the real power of your promotional activities for increasing prescribing and, you know -- this was -- I mean, you have a built-in sort of -- you want to see the effect of marketing, Duragesic is probably the best example of it.
Q. I understand that you've told me that. But I'm really going to ask you to try -- I'm running out of time now, and I haven't asked you about 85 pages of your 95 pages of report about Duragesic and Nucynta. So I'll ask you -- we understand your views about this, but I'd ask you to just try to please focus on answering my question.
MR. RAFFERTY: Just for the record, he specifically answered your question. He said, no, I would never say that at all.

Page 596

MS. LAURENDEAU: And then he went on and on and on.
Q. You would agree that at least some doctors who prescribed Duragesic or Nucynta off-label weren't misled by Janssen's marketing, correct?
MR. RAFFERTY: Object to the form.
A. I certainly wouldn't want to say that every single doctor. But I think that -- there are always exceptions, and there are always individual doctors. But the notion to use this for chronic back pain and osteoarthritis didn't come from any other source other than your marketing.
Q. You would agree that some doctors who prescribed Duragesic and Nucynta off-label were well-informed of the risks all along, correct?
MR. RAFFERTY: Object to the form.
A. Just give me a second to answer that question.
Q. What do you need to look at to answer the question, just for the record?
A. I just want to see what is -- I

Page 597

want to see something about the label. Hold on a second.
Q. I just want to know if you would agree that some doctors were well-informed of the risks of Duragesic and Nucynta all along --
MR. RAFFERTY: Object to the form.
Q. -- when they prescribed it off-label.
A. I think the extent of the -- again, I want it to be precise. I'd want to look at the certain documents.
But in the spirit of time, the extent of the addiction from these compounds over the long-term, I don't think the vast majority of doctors -- the exceptionally vast majority of doctors really understood, in light of this change in American medicine that happened.
So I don't think the vast majority of doctors were well-informed about the real -- I mean, after these -- I mean, these campaigns that minimized collectively the abuse of these products. So, I mean, I think -- I'm not saying there's no one who's well-informed, but

Page 598

I think it was very small.
Q. You would agree that at least some doctors were well-informed of the risks all along, correct?
A. I am sure that there are a couple who resisted this notion that you could use these drugs safely in these conditions.
Q. You think there are only a couple doctors who were well-informed of the risks of Duragesic and Nucynta but prescribed those products occasionally off-label for certain patients?
MR. RAFFERTY: Object to the form.
A. I do need to find -- so I can be precise.
Q. I'm just going to move on. Withdraw the question.
THE WITNESS: Go off the record for a second.
MR. RAFFERTY: She's moved on, Doctor.
THE WITNESS: Thanks.
A. I just want to be able to answer your question precisely.

Page 599

Q. Do you have an opinion, as you sit here today, of how many doctors who prescribed Duragesic and Nucynta -- what percentage who prescribed Duragesic or Nucynta off-label were misled by Janssen's misleading promotion or marketing?
MR. RAFFERTY: Object to the form, asked and answered.
THE WITNESS: Why don't we go off the record. I just need to find one document, and I don't want to take your time.
MS. LAURENDEAU: Okay. We'll go off the record.
VIDEO OPERATOR: 12:06, we are off the video record.
(Recess from 12:06 p.m. until 12:11 p.m.)
VIDEO OPERATOR: 12:11, we are on the video record.
BY MS. LAURENDEAU:
Q. Dr. Kessler, do you have an answer to the pending question?
A. Yes. I don't have a -- I have no

Page 600

opinion on a precise percentage of doctors who prescribed Nucynta were misled. But I think it was a very significant number who were affected by the minimization of the risk of abuse. I think that change in medicine had a major impact on the profession.
Q. Can you name anyone, as you sit here today, who prescribed Duragesic or Nucynta who was misled by Janssen's promotion and marketing and otherwise would not have prescribed the medicine?
MR. RAFFERTY: Object to the form.
A. Yeah, I'm -- I did not conduct, nor would I think it would be appropriate to do, an anecdotal interview. That's not -- I mean, I'm basing it on the data that I have seen.
Q. You haven't spoken with anyone, whether in an anecdotal interview, in the course of your professional career, or through any formal survey or otherwise, who indicated to you that he or she prescribed Duragesic or Nucynta as a result of being misled by Janssen's marketing or promotion, correct?
MR. RAFFERTY: Object to the form.

Page 601

A. I wouldn't rely on the anecdotal kind of comments that are just made to me. I think that would be inappropriate.
Q. And you're not aware of anyone who fits that description, as you sit here today, are you?
MR. RAFFERTY: Object to the form.
THE WITNESS: Gerard, can I just see General 1, please.
MS. LAURENDEAU: What's General 1?
THE WITNESS: Just my notes, please. Just the packet of notes.
MR. RAFFERTY: Can I ask a question?
MS. LAURENDEAU: Sure.
MR. RAFFERTY: When you say, you're not aware of anyone, you mean by name?
MS. LAURENDEAU: Any. Any specific person. I know he holds the opinion that that's generally true. I want to know if he has any specific person he knows of who falls into that category.
A. So let me give you a call note that provides evidence in Cuyahoga. And it ends in

Page 602

just 4, and everything prior is Janssen, Ohio ending in 4.
Quote, Duragesic for chronic back pain and DJD, degenerative joint disease, believed was only used for cancer patient. Discussed patients on Percs and Vics and how to convert, gave core message of our Duragesic, disc. MS, Oxy. Said he would choose Duragesic over them.
So that's obviously a change. I can give you the doctor's name here, but I don't think that would be fair.
Q. Was that a doctor in Cuyahoga County, you said?
A. In Cuyahoga County. I'm just reading from call notes.
Q. What was the date of the call note?
A. 4-14-1999.
(Reporter interruption.)
Q. And that was a discussion about chronic back pain and DJD, correct?
A. Correct.
Q. That was within the approved indication for Duragesic at that time, correct?

Page 603

A. Yeah.
Q. No.
A. No.
Q. You think it was only approved for cancer pain?
A. No.
Q. What was it approved for at the date?
A. You could use it in chronic back pain, but you can only use it in chronic back pain when there was no other alternative. That was the indication. Continuous, around the clock. That's the rub, ma'am.
Q. How do you know that patient didn't require continuous, around the clock and hadn't had other medications fail?
A. That's certainly -- you can -- we only know what we see here. Obviously, this call note says this doctor changed; that Duragesic was for chronic back pain and DJD.
You're right in terms of, if this said Duragesic for chronic back pain when no other alternatives and continuous and around the clock. But if -- you know, if that was the

Page 604

indication that it was being promoted for, it would have said that.
Q. Well, and you don't know what the doctor actually did in response to this information provided by the sales rep, do you?
A. I'm limited to the fact that he says he would choose Duragesic, thought -- over Oxy, as the last sentence. So I know what he's saying. He's saying now he will choose that.
I do not know, you're correct, what scripts this individual -- but I could run -- I'm sure I have that in the IMS if you want to take a look.
Q. You haven't spoken to that doctor, correct?
A. I think that would be inappropriate. So obviously, I'm relying on the record, correct.
Q. Okay. And other than this example from call notes, are you aware of any doctors who you believe -- you've given me one example -- prescribed Duragesic or Nucynta and wouldn't otherwise have prescribed it as a result of Janssen's misleading promotion and

Page 605

marketing?
A. Well --
MR. RAFFERTY: Object to the form.
A. You certainly have documents -- I'm happy to give you all of them and cite them -- that the driving the functionality story versus Oxy, that message --
Q. Rather than --
MR. RAFFERTY: Objection.
Q. Rather than general messages or general activities, I'm focused on specific doctors right now.
Other than the one example you've given me from call notes, are you aware of any instances of any doctors who prescribed Duragesic and Nucynta and otherwise would not have were it not for Janssen's misleading promotion of the products?
MR. RAFFERTY: Objection. I think it's vague, and that's the problem.
It's -- you're saying "instances."
A. I mean, I can tell you -- I can give you -- and the way that your client did this was in the aggregate so that there was --

Page 606

Q. What are you looking at, for the record, please?
A. So I can give you a number of documents. You want to put those on the --
Q. I just want you to identify what you're looking at, and then I'll decide if we're going to talk about it or not.
A. Okay. One is called Duragesic E-Detailing Pilot Program. One is Key Tactics Review. One is Duragesic -- Duragesic Coupon ROI Analysis NRx and Coupon Data Through 2001. And the Ohio Regional Business Plan 2009.
Q. These are documents that you're relying on for your opinion that Janssen's misleading promotion and marketing of Duragesic or Nucynta caused doctors to prescribe opioids and they otherwise would not have, correct?
MR. RAFFERTY: Object to the form.
A. I'm relying on -- that opinion that you just stated, I'm relying on all the documents that I cite in the report, not just these, just so you understand.
Q. But these documents don't provide any examples of specific doctors who have been

Page 607

misled by Janssen's promotion or marketing of Duragesic or Nucynta, correct?
A. I think these doctors provide better evidence than an individual doctor because that's --
Q. That's fine.
A. Let me finish my statement.
Q. We can quibble about that, but --
A. They do. Because they give you exactly the return on investment from promotion -- various promotional activities. And we know what those promotional activities -- what they were for and how they were misleading.
So you have the numbers in aggregate, what the effect is of your promotion, and even in Cuyahoga County and in Summit -- in cities in Cuyahoga and Summit.
Q. But without talking to an individual doctor, you can't testify that any particular doctor was or wasn't misled, can you?
MR. RAFFERTY: Object to the form.
Q. You have to assume that they were?

Page 608

A. No, I'm not assuming anything. What I'm relying on is your company's analysis of how doctors changed their prescribing practices based on the promotional materials that were given and the promotional sales pitches that were given that focused on functionality, et cetera, that we've discussed.
Q. And it's your opinion that those doctors who prescribed Duragesic and Nucynta were misled, correct?
A. Certainly, the campaigns that focused on functionality, on lower abuse that are identified in the report, those campaigns led to the misleading of doctors.
Q. And in order for a doctor to be misled, they had to give more weight to Janssen's marketing than to the product labeling, correct?
MR. RAFFERTY: Object to the form.
A. Janssen's -- Janssen's marketing was so extensive and so sophisticated that it wasn't just, quote, marketing. So it's not a question of --
Q. Can you answer my question. Either

Page 609

you agree with me or you disagree with me.
A. I will.
Janssen's -- it's not a question of Janssen's just, quote, marketing. Janssen got doctors and studied extensively which doctors influenced other doctors.
So it wasn't a question of whether -- you know, some sense of Janssen marketing, but in sort of -- between KOLs and KOL mapping was just exquisitely sensitive. The range from regional advisory boards to the speakers' bureaus, to the E-marketing to doctors, to the alternative channels, to the advocacy groups, to the unbranded publication plans, you knew exactly which KOLs would influence which doctors to prescribe, and your client utilized those KOLs to influence.
So it's -- the sophistication of what influenced doctors versus the label, the label had no chance compared to the sophistication that your company utilized to market because you got other doctors in KOLs to talk to those doctors and changed American medicine.

Page 610

Q. Is it your opinion that these activities you've just described made it impossible for doctors to be aware of the risks of opioid medicines and particularly Duragesic and Nucynta in deciding whether to prescribe them?
A. You infiltrated the medical profession in such a way that it was very hard. You got other doctors to talk -- the most influential, the ones that you said would score five or six on your KOL mappings. The most influential doctors you got to talk to other doctors to talk about things that changed, again, the practice in regard to opioids. So it became -- it was overwhelming in nature and highly sophisticated.
Q. Did these activities make it impossible for well-informed doctors to understand the benefits and risks and make appropriate prescribing decisions regarding Duragesic and Nucynta for their patients?
A. Made it impossible. I would never say anything made it impossible. That would be -- but do not -- do not underestimate the

Page 611

extent to which you infiltrated American medical practice.
Q. Okay. In terms of -- you have some opinions in your report about potential direct-to-consumer advertising for Duragesic, starting at paragraph 286.
Do you recall that?
A. I do.
Q. Okay. Did Janssen ever undertake a direct-to-consumer marketing campaign for Duragesic?
A. It decided not to, after it -- well, it decided not to do DTC broadcasts. Let's put it that way.
Q. And it's true that after several meetings with FDA, Janssen listened to FDA's concerns and did not undertake a direct-to-consumer advertising campaign for Duragesic, even though FDA didn't prohibit it from doing so, correct?
A. Well, FDA was bound by the First Amendment. So, you know, that's -- make no mistake that that's what the issue is here. Just so we understand, that's DTC broadcasts.

Page 612

There certainly --
Hold on one second. Let me just check one --
Q. It's okay. I'll move on. I understand your question. You're looking for something to potentially clarify.
In the context of discussions with FDA, Janssen informed -- if you look at paragraph 287 of your report, Janssen informed FDA that it was looking to market Duragesic to back pain and arthritis sufferers, correct?
A. I apologize. I just have to get my report. Just give me a second.
Q. In the context of --
A. What paragraph, please?
MR. RAFFERTY: 287.
Q. Paragraph 287.
A. Thank you very much. I'm sorry.
Q. In the context of discussions with FDA about potential direct-to-consumer advertising of Duragesic, Janssen informed the FDA it was looking to market Duragesic to back pain and arthritis sufferers, correct?
A. I'm sorry. Market Duragesic to

Page 613

back pain and arthritis sufferers as undertreated. Is that what you're reading there?
Q. I'm not reading it; I'm summarizing it.
A. Let me just read it, then.
Q. Did you answer --
A. I'm just not done. I apologize. I'm a slow reader. I apologize.
THE WITNESS: Can I get the actual document on 287, Gerard, please.
Q. Let me just talk about what you've written about it here.
A. Sure.
Q. So you reviewed the document, and you wrote a summary paragraph in your report, correct?
A. Correct.
Q. And you've described it as saying, Janssen's representative clarified that Janssen's, quote, market research had identified back pain and arthritis sufferers as undertreated and potentially appropriate candidates for Duragesic, correct?

Page 614

A. That's exactly what the document says.
Q. And DDMAC's representative responded to Janssen and said, quote, this was fine, but the message needs to be clearer that the drug is for severe pain, not your everyday back pain, correct?
A. That's exactly what that says.
Q. And so Janssen informed FDA it was looking to market Duragesic to back pain and arthritis sufferers, correct?
MR. RAFFERTY: Object to the form.
A. At what point in time are you talking about?
Q. I'm talking about in connection with this -- discussions in May of 2000 about Janssen's direct-to-consumer advertising plan for Duragesic.
A. Right. So again, this is in context to DTC, but obviously, what you intended as part of your -- your NDA. This is just one conversation that is going on in the context of broadcast.
Q. Right. And so in the discussions

Page 615

pertaining to DTC, Janssen informed FDA one of the things it wanted to advertise to consumers was pertaining to use of Duragesic for arthritis pain and back pain, correct?
A. Correct.
Q. And FDA didn't say, no, you can't do that, did it? FDA said, this is fine, but the message needs to be clear that the drug is for severe pain, not, quote, your everyday back pain. That's what FDA said, right?
A. That's what's said in this memo. What FDA -- obviously, what Nancy Ostrove is bound by the label, so you can't take this as --
Q. I'm just talking about what FDA said.
A. We can certainly say in the context of discussing whether you should do DTC, Nancy Ostrove was -- her recollection was that you would target cancer pain, right?
It's interesting because that was exactly my recollection at the agency, and that was my sense of what Duragesic was for, that there may be some patients, but they would be

Page 616

few. And this again, this is the rub.
You wanted to market for chronic back pain and arthritis.
And FDA -- I said it, and Nancy Ostrove is saying, be careful here. This is not -- this has to meet those indications in essence on the label, and she's using shorthand and saying, you know, this is not your everyday back pain. This better be continuous. This better be continuous; this better be when -- in essence, when there's no other alternatives.
Q. Did the FDA ever send Janssen a warning letter or untitled letter for marketing Duragesic for non-cancer pain?
A. It sent other letters. I don't believe -- again, the answer is no, because that's not what the label says. That's not what the indication -- it couldn't send a label [sic].
Q. Right. So FDA wouldn't send an untitled letter, a warning letter, or take enforcement action against Janssen for marketing Duragesic for non-cancer pain because the label permitted it to do so, right?

Page 617

A. No. I mean, it would have sent a warning letter, right, if it knew that you were prescribing this -- if you were marketing this for non-continuous, non-around-the-clock, non-cases where other alternatives were not tried first. I mean, unless that is prominent in your promotion, there should have been a warning letter. That's what it was indicated.

That was the line that I tried to walk. I tried to give room outside of cancer, right. But it had to be where there were -- no other alternatives would work.

Q. You knew even when you were Commissioner this was a potential issue, correct, and a fine line to walk?

A. I had no idea you would get into a competitive war with Purdue and open this up to chronic back pain and arthritis and not the most severe, limited cases.

Q. Okay. I'm going to -- I have limited time left, so I'm going to ask you a few questions about Nucynta.

A. Let me just get some of this out in front of me. Just give me one second.

Page 618

Q. FDA was aware, even before Nucynta was approved, about the growing abuse crisis, correct?

A. I'm sorry, are you saying FDA?

Q. Yes.

A. I think that's fair, of course.

Q. And FDA was concerned about potential for abuse with Nucynta before it was approved, correct?

A. Absolutely.

Q. Are you aware that Janssen submitted all of its promotional materials for Nucynta to DDMAC or OPDP?

A. I'm not going to take issue with it. The only thing I would say that I -- the record doesn't reflect that that's -- it doesn't mean that FDA reviewed it.

Q. Okay. Is it your opinion that Janssen -- or that FDA may not have reviewed all of Janssen's promotional materials for Nucynta, even though Janssen provided them?

A. That's usually the practice. And in the vast majority of promotional materials that get submitted, certainly after launch,

Page 619

would not get reviewed.

FDA, in certain periods of time, certainly, you know, had a handful of people, maybe four or five, I think the GAO report cited. It would be impossible for FDA to review everything that was -- FDA could not -- I mean, there was a very small fraction that FDA would review of submitted materials. That differs a little on launch.

Q. Do you know -- you don't know, as you sit here today, whether FDA actually reviewed Janssen's promotional materials for Nucynta, correct?

A. I can see what's in -- in the -- in the record. I -- top of mind, I don't recall at this moment.

Q. And FDA's never expressed concern with Janssen's marketing materials for Nucynta, has it?

A. So there's a 2011 letter, I believe, if my memory serves me right, that I would need to get in front of me.

Q. That letter pertains to statements made by -- at a conference by one sales rep,

Page 620

correct?

A. You need to show me the letter, but I will take your stipulation, in the spirit of time. The letter says what the letter says.

Q. FDA never issued a warning letter related to Nucynta marketing materials, did it?

A. It was only that one letter, ma'am.

Q. And that was an untitled letter, correct?

A. Again, I don't have it, but I think you're right.

Q. Okay. I'm going to ask you -- I guess I'm going to jump back to a few of the letters you talk about from FDA to Janssen regarding Duragesic.

THE WITNESS: Gerard, can I get my notebook that's called DDMAC Janssen, please.

Q. So starting at -- I believe it's paragraph 301 of your report, you talk about warning letters that the FDA issued to Janssen regarding Duragesic.

A. Hold on one second, please. Paragraph 301.

Q. 301 talks about a September 2004 warning letter to Janssen regarding a file card, correct?
A. Yes.
Q. And paragraph 304 talks about a March 5th, 1998 DDMAC warning letter to Janssen regarding promotional posters for Duragesic, correct?
A. Yes, ma'am.
Q. That letter was actually an untitled letter, wasn't it?
A. Did I make a mistake on the March 5th letter, are you saying?
Q. I believe you did.
A. Okay. Then I'll take your correction on that 19 -- the letter says what it is. I take -- I'll take notice on it.
Q. And in paragraph 305, you reference a March 30th, 2000- --
A. Let me just put a footnote. 19 -- yeah, let me clarify the answer to that question. As I said earlier, the issue back at that time, and I have to refresh my memory, don't take the title of the letter as -- at

different points in FDA's history, we titled these things -- I certainly titled this differently.
If you go to the last page on page 3 of this 1998 letter, it says, Janssen should immediately suspend all promotional activities, and Janssen should submit a written response on or before March 20th.
The general rule in compliance and the general rule in the industry, when you are being -- you should -- and gives you a date to do this, that -- I'm not sure FDA in 1998 made a distinction, but I think it's fair to call this in -- I use a little W in paragraph 304, and I would stand by that, by the nature of this letter and the way it's written.
We just went back and forth, although we had warning letters, we had different title letters and different points in time had different policies.
Q. Okay.
A. Clearly it was a warning letter, a little W, warning letter.
Q. Okay. The -- I'm going to ask you

some questions about the 2004 warning letter.
I guess before I do that, can you look at paragraph 306 where you're offering some opinions about call notes of Janssen sales reps?
A. What are we on, 304?
Q. 306.
A. 306. Thanks, ma'am.
THE WITNESS: Can I get my book on 306, please.
Q. So in paragraph 306, you state that the call notes of Janssen's sales representatives show that into 2004, they were frequently promoting Duragesic to prescribers for lower back pain and arthritis, correct?
A. Yes.
Q. And for that, footnote 625, you cite 11 calls in 1998, four calls in 1999, one call in 2003, and 11 calls in 2004, correct?
A. That's exactly what I say. And I also say, see also schedule 11.
Q. And so you cite specifically to 27 calls, correct?
A. I had to add them up. I've got to

look how many are in the schedule. I have not -- I mean, I can do that now, but I don't want to take the time.
Q. And these examples are where you say, Frequently promoting Duragesic to prescribers for lower back pain and arthritis, these examples you cite are out of how many calls did Janssen sales reps make to potential Duragesic prescribers during this at least six-year period that's encompassed by your review?
MR. RAFFERTY: Object to the form.
A. I'd have to go check that. I can go back and check the number of call notes that I had access to.
Q. And you note that some of these calls indicate that sales representatives were also citing to the Milligan and Simpson studies referenced in the sales bulletins noted above in promoting Duragesic for lower back pain, correct?
A. Correct.
Q. And for that you cite one example, correct?

Page 625

MR. RAFFERTY: Object to form.
A. That's what the report states.
Q. Okay. Are you aware --
A. I don't think there's any question, right. I think you look at the totality of evidence here, your client was certainly promoting this for chronic back pain. I mean, the ads themselves show that.
Q. And that was consistent with the indication, correct?
A. No, of course not.
Q. Okay.
A. Chronic back pain, either take Nancy Ostrove or take my -- when there's no other alternative therapy, when it's severe and around the clock, the whole thing was not to do this -- I mean, not to open the door. That was the change.
Q. Okay.
(Exhibit Kessler-24 marked for identification and attached to the transcript.)
BY MS. LAURENDEAU:
Q. I'm going to hand you what I'm

Page 626

marking as Exhibit 24.
A. Thanks.
MR. RAFFERTY: What number is this?
MS. LAURENDEAU: 24.
MR. RAFFERTY: Thank you.
A. This is the -- this is not the 200- -- I'm sorry, I have 1998 here; is that correct?
Q. I gave you the wrong one then, sorry.
A. I'm sorry if I -- I have 200- --
Q. No, I gave you the wrong one. Let me switch that.
A. Okay, thanks.
Q. Sorry about that. Here's 2004, Dr. Kessler.
A. Thank you so much, ma'am.
Q. Okay. So this letter on page 3 is talking about a file card, and it's --
A. Do you want me to just --
THE WITNESS: Parvin, can you just pull up the file card out of here -- or somebody just pull up the -- Lesi -- I'm sorry, I apologize -- just pull up the

Page 627

file card so I have that at the same time.
MR. RAFFERTY: What page are you on?
MS. LAURENDEAU: Page 3.
Q. Under Conclusions and requested actions, the letter states, The file card makes false or misleading safety claims or unsubstantiated effectiveness claims for Duragesic, correct?
A. I just want to -- yes, that's what it says.
Q. Okay. And isn't it true that false and misleading is used by the FDA to mean there's no substantial evidence or substantial clinical experience to support the claim?
A. False or misleading can mean a number of things.
Q. And FDA uses false or misleading to mean there's no substantial evidence or substantial clinical experience to support the claim, correct?
A. No. It's more complicated than that. False or misleading could be the

Page 628

admission of certain facts. It was the net impression we talked a little about yesterday. So it's more -- substantial evidence is certainly a part, but I wouldn't want to say that false and misleading equals substantial evidence when it's used.
I mean, if you don't give a fair balance, for example, that could be -- there are whole things that go into what's misleading and omissions, and it's defined in the regs.
Q. Okay. As it relates to the safety claims made in the file card, FDA isn't saying here that Janssen provided no evidence to support the safety claims in the file card. It's saying that it shouldn't have relied on the DAWN data to support the claims, correct?
MR. RAFFERTY: Object to the form.
A. Hold on one second. Just let me see. You're reading that in the -- hold on one second.
Q. I'm not reading from the document; I'm summarizing the issue. If you don't remember, that's fine.
A. No, no, no, I remember this. I

Page 629

just don't remember every single sentence. Just give me one second.

This is not just about DAWN data. This is also about claims about functionality, and your company was fully aware that it did not have appropriate data and evidence with regard to functionality. I think that's also in this letter.

Q. Okay. If you go through the letter, each of the claims that FDA takes issue with, it says, we're not aware of substantial evidence or substantial clinical experience to support this claim.

A. Certainly that's -- with regard to functionality, your company didn't have that evidence. That's correct.

Q. Okay. As it relates to the safety claims, Janssen relied on DAWN data, correct?

A. Well, I -- sometimes these effectiveness claims are safety claims. But depending on what -- how you're characterizing it, it certainly dealt with DAWN data and the issue of lower reported rates of abuse. That's what it's relying on for that section.

Page 630

Q. Well, FDA broke down this warning letter into false or misleading safety claims and unsubstantiated effectiveness claims, correct?

A. But it did not break that down in the conclusions and requested actions that you read me. It's using false -- it says, False or misleading safety claims and unsubstantiated effectiveness claims. So again, depending on where you think that false or misleading modifies, it could be both.

Q. Have you reviewed Janssen's response to the 2004 warning letter regarding Duragesic?

A. I may have seen it. I tend to try to do that. But I don't have it -- I don't recall, sitting here.

Q. Do you recall that Janssen agreed to remove the file card from its circulation?

A. I believe that's correct.

Q. And Janssen agreed to issue a correction letter?

A. I'm fully aware of that.

Q. Okay. And FDA didn't take any

Page 631

further action with respect to the claims in the 2004 warning letter, did it?

A. I believe that's correct, after the corrective action was taken.

Q. FDA didn't bring any type of enforcement action against Janssen, did it?

A. It did not.

MS. LAURENDEAU: Okay. I am unfortunately out of time, so out of respect to my co-defendants and to give them time with you, I obviously, like those who came before me and those who will come after me, would just like to note that I have much, much more that I would like to do with you, and particularly given my conversation with Mr. Rafferty on one of the breaks about testimony you may give regarding Noramco, which essentially he just said you're going to testify to what -- or potentially testify to what you told me, which I understand you view as facts, we view as opinions, and we view as facts and opinions or alleged facts and

Page 632

opinions that were not in your report and we weren't on fair notice that you were intending to testify as to those subjects.

So we reserve all rights, including the right to ask for the opportunity to continue with the fun and depose you again on another date prior to trial.

THE WITNESS: Let me say something --

MR. RAFFERTY: And to just --

THE WITNESS: Thank you, Counselor. I'm sorry.

MS. LAURENDEAU: Thank you.

MR. RAFFERTY: Yeah. And just for the record, obviously, we disagree with the assessment in terms of the time and, in terms of the assessment, in terms of the issue regarding the super poppy.

I think -- it was disclosed, we believe it's facts, and we'll deal with it later, I guess.

MS. LAURENDEAU: Thank you, Dr. Kessler.

Page 633

THE WITNESS: Thank you, Counselor.
May I take a break? Actually, we may take a bigger break, right?
VIDEO OPERATOR: 12:49, we're off the video record.
(Recess from 12:49 p.m. until 1:41 p.m.)
VIDEO OPERATOR: 1:41, we are on the video record.
EXAMINATION
BY MR. GALLAGHER:
Q. Dr. Kessler, good afternoon. My name is Richard Gallagher, from Ropes & Gray, counsel for Mallinckrodt.
A. Good afternoon, Mr. Gallagher.
Q. Are there any opinions relating to Mallinckrodt that are not set forth in your report about which you intend to testify at trial?
A. No, I don't think so. I think all my opinions are -- well, either in my report or -- if we stop -- if you want to stop now, I would say the answer is, my report.
If you ask me questions, I may have

Page 634

opinions, obviously, to your questions that you ask. So -- but we can discuss those.
But again, it's anything that I -- in my report or to which I testify with you this afternoon, sir.
Q. Okay. So sitting here right now, I can be confident that what you've written in your report captures what you intend to testify about at trial with regard to Mallinckrodt; is that correct?
A. Yeah. I mean, I think the report aims to do the four corners, but there's a lot of material that we may end up talking about. I think there is -- again, I think there is -- it doesn't change my opinions.
I mean, there's one point that I think is a little factual, but it depends whether you ask me, and I'll be happy to tell you about it. Your call. But it's not -- I'm not going to give a different opinion.
But documents say certain things, and they're on -- they're on my reliance list, to the extent to which you want me to point them out. They may not be fully stated in the

Page 635

report.
Q. Do you recall the two branded products from Mallinckrodt that are the subject of your report?
A. Exalgo and Xartemis? I mean, I've never pronounced it correctly. I apologize.
Q. I may not have either.
A. Yeah. So we're both -- we're both in the same boat.
Q. Sitting here right now, do you intend to render opinions at trial on brands other than those two from Mallinckrodt?
A. No. Well, see, you use the word "brands." I think that there is the issue of generic oxycodone that I do think is referenced within the scope of my report. I think, just to -- that's certainly not in the sections on Exalgo and Xartemis --
How are we going to refer to it?
Q. Xartemis?
A. Yeah, that's fine. Thanks.
So they're not Exalgo and Xartemis, but there is a section of the report -- to the extent the collective defendants engaged in

Page 636

class-wide opioid promotion, sort of unbranded promotion, that had an effect not only on the brands that we -- Exalgo and Xartemis, but also had an effect on generic oxycodone.
So to the extent that in sales, that affected generic oxycodone, that's in the report.
Q. Is there a section of your report that describes this phenomenon?
A. Yes, there is. It's discussed pretty extensively in the report that much of the unbranded advertise -- sorry -- the unbranded promotion that took place was about opioids, less abuse, pseudoaddiction. Much of that -- that sort of rose the water level, if you would, for the whole class.
So that rising the water level affected not only the name brands but obviously the generics, and your client was a very significant generic manufacturer.
Q. Why don't we go to page 20 of your report.
A. Yes, sir.
Q. Do you see where there's a heading

Page 637

that says, Promotional information needs to be evaluated by the totality of the impression it creates?
A. Exactly.
Q. And you see there's a citation to the FDA's industry guidance?
A. Correct.
Q. Is that the standard you applied to come to a conclusion as to whether promotional materials were misleading or not?
A. That's one of the factors that is used in the evaluation. This is how you evaluate risk communication specifically in promotional materials.
But there are other aspects, such as overstatement of efficacy, understatement -- so there are other -- there are other aspects and standards that are also set out in this section that --
But when it comes to risk communication, I think that would be fair.
Q. Would it be risk communication to doctors?
A. Depends what the promotion is aimed

Page 638

at, I think would be a fairer statement, sir.
Q. Before the break, you talked about the collective impression of doctors and gave testimony about that. Do you recall?
A. Yes.
Q. You've given a lot of testimony about, in your opinion, promotional activities that you believe were misleading.
Who do you believe that those activities or statements misled? Is it primarily the doctor community?
A. That's a good question. Let me think for a second, if I may.
As it relates to prescribing behavior and that change in prescribing behavior, I think it is -- it's doctors, it would be nurse practitioners, it would be those who had prescribing, you know, responsibility.
But I think it changes. I think it's a little broader. I think it would be health professionals, I mean, who were -- who receive promotional messages. So it would be the target audiences of those promotional messages.

Page 639

Q. So when you talked about collective impression that was made by promotional activities, you were talking about a category broader than doctors; is that fair?
A. Well, they certainly -- yes. I think it's fair to say the promotional messages you see in the campaigns affected pharmacists, nurse practitioners, managed -- you know, a whole range of individuals who are health -- who touch the health care system. I think you see various campaigns directed against different professionals.
Q. Are the professionals that matter in terms of prescriptions the professionals that write prescriptions?
MR. RAFFERTY: Object to the form.
A. Primarily, yes. As I said yesterday, I'm not getting into -- I'm not going to testify about pharmacists, but you certainly --
You know, just answering your question fully, the pharmacists certainly matter when it's -- when we're talking in terms of prescriptions, because they're the ones

Page 640

that -- they're professionals who fill those prescriptions. So they matter, sir.
Q. The heading says that, Promotional information needs to be evaluated by the totality of the impression it creates.
Do you see that?
A. Yes.
Q. What does that mean, "the totality of the impression"?
A. So what FDA -- the old DDMAC, you know, the regulations and -- is that you can't -- if you have a number of different components of information, for example, on a sheet, you have to look at the graphics, you would have to look at the audio, you would have to look at the words.
If I say, you know, This drug, you know, causes leukemia, and somebody's walking on the beach and the ad -- and the sound is the music and everything, you just have to look at all those -- you should look at all those factors that are absorbed by the -- you know, the person to whom that promotion is aimed at.
Q. Would you also consider the label

Page 641

or materials outside of the promotion being examined?
A. Say that again. I'm sorry.
Q. Would you also -- in doing this assessment of the totality of the impression, would you look at the label and consider the information conveyed by that?
A. Generally, in DDMAC, you know, you would do this by the -- I mean, I think you would probably consider it, but obviously, a 6-point font on the last page is not going to be considered in the impression that the first six pages of a sales aid in 40-point font and color would have.
You know, so generally, when one is talking about the material, it's per -- it's per -- what's the best way -- it's per -- per impression, right.
So it's the impression of the piece that conveys, and it's usually the aid itself, but I wouldn't want to exclude the label, if it's attached.
Q. You said before the break that you don't believe that the vast majority of doctors

Page 642

were well-informed of the risks in addition to the benefits.
Do you remember that testimony?
A. I remember something generally.
MR. RAFFERTY: Object to the form.
A. I don't remember the exact testimony.
Q. You testified, I'll represent to you, that you don't believe that the vast majority of doctors were well informed of the risk in relation to the benefits of certain of certain products.
Do you believe that was the case for the two Mallinckrodt products that you've given opinions about?
A. So we can take them separately. I think there were misleading characteristics of -- that I point out and that were, you know, again, part of this, you know, less peaks, smoother, less -- and what that conveyed with regard to lower abuse potential.
So were they really informed of the risk? So that would diminish their information of the risks.

Page 643

Q. When you say "they," who are you talking about?
A. No, you had -- the question was, that I'm reading, do you believe that the vast majority of doctors are really informed of the risk of the product really informed of the risk of the product?
Q. So when you --
A. So I'm talking about -- I'm sorry -- about doctors, sir. So it would be who would be --
For example -- I mean, in the paragraphs, I point out that certain graphs give an impression about peaks and troughs, and that sort of implies that it's safer, and that means that you're not fully informed.
Q. So you personally believe that doctors weren't well-informed of the risks from the Mallinckrodt products?
A. I think that the standard -- no, the way I would say it is, there are certain requirements that the information needs not -- it's important it not convey misleading information because we know that --

Page 644

The reason we have that sort of requirement is because that -- I mean, it's sort of given that if you're misleading in the ads, doctors are not well-informed.
I don't have a survey on particularly -- on each point, but I can tell you that's the reason why the standard is what the standard is.
Q. Why don't you have a survey on each point?
A. Well, because I'm sort of limited to the record.
And there are surveys, and in certain manufacturers, I can tell you exactly doctors' perceptions, I can tell you what the return on investment, I can tell you what the effect of this promotional campaign or this promotional element is on the number of prescriptions. I can even do that to a certain city.
But it depends on what the record has, sir.
Q. What surveys have you undertaken with regard to doctors' impressions of

Page 645

Mallinckrodt products?
A. I restricted this report to the record. I've not gone outside of the record. I was not asked to do that, and I've not done that.
Q. Do you have any objective evidence of what doctors believed about Mallinckrodt's products?
A. Sir, let me just -- let me just refresh. So there are -- for example, you have --
With regard to Mallinckrodt and Exalgo specifically, I can tell you what the message recall was at a certain -- at certain points in times based on, you know, certain data.
So there are those -- you know, the unaided message recall, whether there was a recall that there was less abuse, misuse, overdose potential.
There is some information about what the doctors' recall was after -- sorry -- after promotion.
Q. So that's the evidence that you

Page 646

have about the collective impression of doctors about Mallinckrodt products?
MR. RAFFERTY: Object to the form.
A. I mean, that is what you have, both the strategy documents and what the message development is and what the recall is. I mean, that's among what I have.
But if you want to measure it, you would measure it by recall, and that's what I have, and I'm limited to what the company has.
Q. Do you have any objective information about doctors' collective impressions of the risks that would arise for Mallinckrodt's products?
A. Only to the extent that in those recall documents, those message recall documents -- minimal, less abuse -- a certain percentage had that impression -- that recall.
What was the main message of the -- and, again, I'm going to apologize -- is it Covidian [ph] or Covidan [ph] -- of that sales representative conveyed about Exalgo.
So we know what their impression was from those message recalls.

Page 647

Q. And those collective recalls are all you have on that point; is that correct?
MR. RAFFERTY: Object to the form.
A. I'd want to go back to review my report. I mean, any information I have is in either my report or in the reliance list.
Q. Did you become aware of a survey of Ohio physicians on opioid prescribing behaviors in connection with your work on this matter?
A. I've become -- I'm not sure. Top of my head, I just don't have a memory right now. I've seen certain documents, but I'm not sure I've seen what you're referring to.
Q. When you began work on this matter, did you ask to receive all information which would provide information about how doctors perceived risks from Mallinckrodt's products?
MR. RAFFERTY: Object to the form.
A. No, I didn't ask specifically that. I didn't want to be fed information. I insisted that the entire database be given to me so -- unencumbered. I may at certain times have asked for certain things, but I searched the database.

Page 648

Q. Did you search the database for survey information about doctors' mental impressions?
A. I'm not sure I put those mental impressions in. I may have used recall messages, other things. Those kinds of surveys I may have either asked for, but I didn't use -- I don't believe I would have used the word "mental impression." It's not something that -- it was not the lingo of the recall surveys that I'm used to seeing in the industry.
Q. Do you have any expertise in analyzing how consumers will assess and interpret information that's disclosed to them?
MR. RAFFERTY: Object to the form.
A. Yes. I mean, I have been -- you know, I had to make the hard call sometimes, and not the only one, but does FDA bring an enforcement action whether something is false or misleading, and, you know, what the evidence one needs if one is going to do a misbranding action.
I was the guy who seized orange

Page 649

juice because it was fresh, right. So I mean, I had to understand exactly that question of how it was perceived.

So I mean, I've both taken a marketing course, you know, in business school as well as had to do it on the job.

Q. So you made enforcement decisions at FDA relating to where you had to make judgments about perception of consumers in the market. Is that fair to say?

A. I think -- I mean, I don't want to say that I did this alone. I certainly did it with my colleagues at the agency. But at the end of the day, they go, Kessler, what are you going to do here? In a number of instances, what do you want me to do? And I would make the decision. But that would be rare.

I don't want you to think that that's the run-of-the-mill kind of decision-making the agency where the Commissioner is making decisions, but I certainly have made those decisions.

Q. So do you believe that at the FDA, where employees make enforcement decisions,

Page 650

that makes them experts on consumer understanding of information?

A. Well, you know you're going to be the named defendant in court, you better be an expert, because if I'm going to take an enforcement action, my name is going to be as the defendant, I mean, or my boss' name is going to be -- the Secretary is going to be named as defendant. So you learn pretty quickly and pretty thoroughly when you're on the line here.

And again, I had some training on marketing. I've also -- there was a lot of -- all of DDMAC really is the question of what's false or misleading, you know.

I tried hard to do it the best I could. I think I learned a lot. I certainly think I understand it in the context of FDA regulation. I may not know it in terms of the jolly green giant, right, and -- but I think in terms of FDA-regulated products, I probably understand false or misleading with the best of them.

Q. So you believe your understanding

Page 651

of whether or not doctors receive false and misleading information about Mallinckrodt's products is just as good as if you had undertaken an objective survey to answer that question?

A. No. It's different information. I mean, it's different information. I have the information. I have -- I can look at a piece and say, it looks false or misleading. It conveys certain impressions. Especially when that piece is in context.

In this case in Exalgo, when you're talking about peaks and troughs, we know that that -- that those promotional messages ended certain people up, you know, in criminal violation.

This was out of a -- I don't know what the right word is -- out of a -- I want to be careful here. I mean, these messages -- I don't want to say script, I don't want to say playbook -- these messages sort of -- did we that we see early on about lower abuse potential, less peaks, less troughs, that impression, that was a theme, I think, through

Page 652

these opioid products, and so it's in the context of that. This is not just a one-off.

I think if I saw your -- saw something just one slide alone, it's one thing. But one slide in the context of these themes where these themes are adjudicated in essence even criminally as misleading, even with their unique aspects, I mean, it's that totality of that evaluation.

Q. What FDA enforcement -- what enforcement -- FDA enforcement actions are you aware of involving Mallinckrodt's two branded products that you opine on?

MS. FREIWALD: Object and move to strike the part of the answer that misrepresents the record.

A. I'm not sure I opine -- everything that I'm opining on with regard to -- is in the report, and I don't believe there is any enforcement action. I don't have a memory of any enforcement action.

Q. So if the FDA decided not to pursue enforcement action against Mallinckrodt for these two branded products, by your standards,

Page 653

should we conclude that there was no misrepresentation in the promotion?
A. Of course not.
Q. How is that consistent with what you told me earlier?
A. Well, first of all, FDA doesn't catch everything. Limited resources. I mean, you know, not everybody gets caught for speeding, right. Just because you don't get cited doesn't mean you're home free and you're not false or misleading.
Q. What have you done to test the FDA's resources and its impact on the ability to bring enforcement actions against Mallinckrodt?
A. I can't tell you anything specific with regard to Mallinckrodt. I can tell you that the record is full of documents that shows FDA's resources specifically in the DDMAC area. Both the General Accounting Office as well as the Institute of Medicine has studied this extensively with regard to the industry as a whole, and the FDA's resource -- I mean, those reports deal with the totality of resources FDA

Page 654

has to deal with Mallinckrodt and everyone.
Q. When you were doing your work in relation to your opinions on Mallinckrodt, did you ask to see all marketing and promotional materials that Mallinckrodt had made available?
MR. RAFFERTY: Objection, that's work product. Communications between the expert and the attorney are clearly out of bounds.
Q. Did you?
MR. RAFFERTY: No, do not answer that question.
MR. GALLAGHER: Are you taking the position that there is a work product privilege between counsel and this expert?
MR. RAFFERTY: Yes.
MR. GALLAGHER: And you're instructing him not to answer the question?
MR. RAFFERTY: I am.
Q. Did you think it was important in doing your work to review all promotional materials in the production about Mallinckrodt?

Page 655

A. I thought it was important to have the full database available to me. I tried to review as many documents as I could, as it was humanly possible within, you know, reasonable time constraints of life.
So I did ask for the entire database, but there are millions and millions and millions of pages, that it was just beyond my capability.
So I did search. It was important for me to see the strategies as well as those promotional materials that were -- that was important. So I tried. But there's a limit to what I -- I don't -- you can't see every promotional piece.
Q. So it's fair to say that you did not review all of the Mallinckrodt promotional materials, correct?
MR. RAFFERTY: Object to the form.
A. I had access to that. I wouldn't want to sit here today -- I don't have a recollection of exactly -- I mean, I've looked at thousands and thousands and thousands of documents, including numerous Mallinckrodt

Page 656

documents, and many were promotional materials, but I can't tell you what percentage I looked at or all or -- and I just -- I don't have that memory.
Q. So you don't know?
A. Exactly, sir.
Q. Did you come across Mallinckrodt promotional materials that accurately disclosed the relevant risk relating to the two products about which you opine?
A. I think there are aspects of -- there's aspects of the promotional materials that I don't have any objection to. I think my report points out the ones that I do. I don't want to say that they're all -- all those statements are misleading, no. I point out the ones that are misleading.
Q. Why did you not include in your report disclosures that accurately described risks?
A. Well, I can't -- the reports are 350 pages. I tried my best to include as much as I could. But I can't -- you can't describe everything, Counselor. I mean, I just --

Page 657

The issue here -- the central issue to me that I focused on were issues of especially abuse liability, this change in medical practice, how we became -- the medical profession ended up prescribing these more loosely and overcoming -- what had to be done to overcome that fear of addiction. So that's what my report in significant part focuses on.

And I think with regard to Mallinckrodt, I talk -- the issues that I deal with are, you know, focus on certainly I think less abuse liability.

MR. GALLAGHER: I have no further questions, Dr. Kessler.

For the record, I'm ceding the balance of my time; for the reasons that the parties have discussed throughout this deposition, the manner of the questioning, compressing the time available for all the defendants, so I join and Mallinckrodt joins in the objection relating to them.

MR. RAFFERTY: Plaintiffs take the same position. No, no, let me rephrase

Page 658

that. That might not read right.

Plaintiffs disagree.

MS. LEVY: And for the record, on behalf of the other defendants who have not yet gone, we dispute the characterization of ceding time. I think you mean you're passing the witness. But as we would dispute the division of time, I think that you might have cut into our time, not ceded us extra time. But we can discuss that.

MR. GALLAGHER: I don't mean to imply that we are having our time stolen away from us, but that the circumstances are requiring us to share time.

MS. LEVY: Thank you for clarifying.

MR. GALLAGHER: Dr. Kessler, thank you.

THE WITNESS: Thank you, Counselor. Can I ask who's going next.

MR. GALLAGHER: Off the record.

VIDEO OPERATOR: 2:13, we are off the video record.

Page 659

(Recess from 2:13 p.m. until 2:23 p.m.)

VIDEO OPERATOR: 2:23, we are on the video record.

MS. FEINSTEIN: Thank you.

EXAMINATION

BY MS. FEINSTEIN:

Q. Good afternoon, Doctor. We met briefly before the deposition. I'll reintroduce myself for the record. My name is Wendy West Feinstein. I represent the Teva defendants in this litigation.

I'll be asking you some questions, and as we've all noted, we have limited time, so I'd request that you do your best to listen to my questions and answer as concisely as you can, okay?

A. Thank you, ma'am.

Q. Thank you.

So before we get started on the substance, I want to understand the scope of your report with respect to my client regarding not only the scope of the products that you're covering, but also the time scope.

Page 660

So as I look at your report, I see two products that you reference, Actiq and Fentora; is that right?

A. Yes.

Q. And you render opinions with respect to Actiq and Fentora, but no other Teva or Cephalon products, right?

A. Correct.

Q. Earlier today you mentioned that there are a lot of company changes with many of these organizations, and so you focus more on products than company names; is that right?

A. Well said.

Q. Just to clarify for the record, some of the documents that you reviewed have the Cephalon name on them, right?

A. Correct.

Q. And those relate to Actiq and possibly Fentora; is that right?

A. Yes.

Q. When today, if I use the phrase "Teva," can we understand that to include Cephalon?

A. Thank you.

Page 661

Q. And you will agree with me that that --
A. Yes.
Q. -- phrase will cover both?
A. Yes.
Q. Do you also render any opinions with respect to any of the companies that Teva acquired that manufacture generic opioids that are also defendants in this litigation?
A. The only generic oxycodone that I think is in the scope has to do with Mallinckrodt. There is obviously the issue of generics from Actavis and others, but -- so the answer that I gave to your prior colleague I think would hold across the board here. And I can just restate it so it's clear.
To the extent the opioid manufacturers contributed to a change in the prescribing of opioid -- the class of opioids, that would refer to affect both branded -- especially unbranded promotion is going to raise the prescription level of both branded and generics.
But that -- that's the -- that's

Page 662

sort of where I -- where I enter an opinion on, that when you do unbranded promotion for a class, and that class is opioids as opposed to -- I'm going to apologize, I'm going to probably use the word "Actiq."
Q. That's fine.
A. But Actiq or Fentora, then it affects all, including the generics, and that is covered in the report.
Q. So just to make sure that I understand your opinion and so that we have it clear on the record, any opinion that you render related to generic opioids would also apply to any branded opioids that are not involved in this litigation but that benefitted from what you have opined is improper unbranded marketing by the defendants in this litigation?
A. I have to admit --
MR. RAFFERTY: Object to the form.
A. -- ma'am, you've just stumped me. My head is spinning. I apologize. I just -- maybe it's the hour. I don't know if we're at hour 12 or so, not consecutively, but I just didn't follow. There are too many unbrandeds

Page 663

and brandeds in there.
Q. So you have no separate opinion with respect to any of the manufacturer defendants or Teva regarding the manufacture of generic opioids, right?
MR. RAFFERTY: Object to the form.
A. There is a section of the report that talks about generic oxycodone of Mallinckrodt. That is singled out at one paragraph of the report.
Q. Okay.
A. But with that exception, the report -- I think we're saying the same thing.
Q. Okay.
A. We're talking about the class of opioids and recognize that generics are part of that class of opioids.
Q. Fair enough. Thank you.
I also want to clarify, yesterday it came up and then today you mentioned a product that was formerly on the market that was manufactured by Cephalon and a predecessor of Cephalon and Teva, which is Oralet.
A. What was the name? It started with

Page 664

an A, I believe. The manufacturer --
Q. Again, I don't have it at the tip of my tongue.
A. The manufacturer started with an A, if I remember. That was Oralet. It was a --
Q. Right.
A. It was the predecessor product -- maybe I'm using that word incorrectly, but the predecessor product to Actiq. Same formulation, I believe, essentially different indication.
Q. Different dosing, different indication, not at issue in this litigation, right?
A. Oralet is not. I've asked. It is not an indication -- it's not at issue in this case, correct.
Q. And your opinions in your report, which is Exhibit 1, contain no opinions about Oralet or any action of Teva related to Oralet; is that right?
A. That's exactly correct. The only footnote if I could put there, ma'am, is that it obviously was a part of my FDA experience

Page 665

and my dealing with opioids and restricted distribution.

So it may be a factual issue, but no opinion with regard to the Oralet -- companies on Oralet not at issue here, other than factually how -- I mean, how I handled opioids.

Q. Your involvement factually and your involvement recommending a limitation of no marketing for Oralet, correct?

A. Correct.

Q. So --

A. Among other things.

Q. -- you give -- but you're not opining that Oralet is a part of this case?

A. It is not, to my understanding.

Q. Your opinions related to Actiq and Fentora appear to me in your report to be limited in time. Is that right?

A. I would -- the way I would phrase it, if this is helpful, I think they're limited to two real issues. And to those issues, we can decide what time frame. But one really is off-label indication, and the second is failure

Page 666

to comply with the risk maps.

So those are the two sort of issues, and then we can discuss the conduct and the evidence under those two time periods.

Q. So before we get to the substance, let's talk first about Actiq or Actiq. It can be pronounced either way, I think. I'll probably say Actiq, but I think --

A. No, you're right. It's your client, and I --

Q. So with respect to Actiq, you've got two opinions; is that right? And feel free to look at your report. The first one I see on page 254, which is, you opine that Teva marketed Actiq for non-malignant pain for which safety had not been established by substantial evidence.

A. That's a heading, and I believe it's carried forward exactly -- maybe not exactly in those words, but almost identical in paragraph 474.

Q. Right. And 474 sort of summarizes the paragraphs that precede it. And you summarize in paragraph 474 of Exhibit 1, In my

Page 667

opinion, Teva marketed Actiq for non-cancer pain, an indication that lacks substantial evidence to support safety.

Correct?

A. Exactly.

Q. So that's your first opinion about Actiq, right?

A. Yes.

Q. The marketing materials that you refer to in your report all pre-date -- or are all dated 2006 or earlier; is that right?

A. I'll take your -- not to waste your time, I think that is correct.

Q. Do you have any opinions regarding the marketing of Actiq after 2006?

A. I'd have to go back and look at the reliance list and look to answer your question precisely, but you can base -- I mean, I think it's fair to say that what's in the report and the evidence in the report is what I will focus on, unless there's something in the reliance list that I've missed.

Q. Are you aware that Teva ceased marketing of Actiq in 2006 when Fentora was

Page 668

approved?

A. I think I do recall that.

Q. So does that help you confirm for me that your marketing opinions relate to marketing from 2006 or earlier?

A. I think that would be correct.

Q. At all times that Actiq was marketed, it was identified and characterized as a CII product; is that right?

A. Of course.

Q. At all times that Actiq was marketed, it was subject to a risk management program; is that right?

A. Yes. It would not have been approved but for that.

Q. And your second opinion relates to the risk management program -- your second opinion related to Actiq. Is that right?

A. The second opinion --

Q. And we can see it just continuing actually in your report.

A. Yes. I mean, I think that -- well, I think that that deals with off-label marketing in general, and the audits and the

Page 669

requirements under that.
Q. And if I could direct your attention, sir, please, to Exhibit 1, the section --
A. Exhibit 1, my report.
Q. Which is your report, yes, sorry. Sorry. I'm referring to it by the exhibit for the record, but let's call it your report.
A. Sure.
Q. Your report, the opinion regarding the marketing of Actiq begins in paragraph 475 and continues through paragraph 482, which is on page 260.
A. That's the marketing as it failed to comply with the risk management strategies.
Q. Right.
A. And what was done -- yes. And let me know if you want me to pull those documents.
Q. Yeah, and if at any point you need to refer to the document --
THE WITNESS: Gerard, can you just give me the notebook kindly that begins 475 so I can have it and hold it, please.

Page 670

Q. So the risk management program that you noted a moment ago is a part of the approval process -- part of the approval for Actiq, correct?
A. Yes, certainly that's correct.
Q. And understanding that you don't have the -- any of the versions of the risk management program in front of you, do you recall whether that risk management -- strike that.
Do you recall that the Actiq risk management program required Teva to report quarterly to the FDA about certain things?
A. There was surveillance and monitoring to determine the effectiveness, I mean, of -- and I think it's exactly to provide a quarterly report to FDA compiled from all data collected by the methods described under the surveillance and monitoring programs and intervention, and it will describe and provide data on any concerns of off-label usage.
Q. As a part of rendering your opinions regarding Teva's compliance with the Actiq risk management program, did you review

Page 671

all of the quarterly reports that were submitted by it to the FDA?
A. I'm sitting here today, I'm -- to be honest, I'm drawing a blank. I'd have to go back and just review the quarterly -- well, I'd have to go back and review that.
Q. You're not rendering an opinion that Teva failed to comply with its quarterly reporting obligations; is that right?
A. No. I think my opinion, if I can be precise, it was contrary to the key -- the marketing was contrary to the key messages in the FDA-mandated risk map.
Q. Do you recall -- strike that.
Did you see in your review of materials regarding Actiq any findings or determinations by the FDA that Teva failed to comply with the risk management program for Actiq?
A. No. I'd have to go back and obviously look at the enforcement action that was -- I mean, I have it -- I'd have to go back and do some more homework. I don't -- I don't want to testify one way or the other on that.

Page 672

I just don't know.
Q. You recall that the quarterly reports that Teva submitted regarding Actiq included reports of adverse events for off-label use, right?
A. I believe I do have some familiarity with that, yes.
Q. Is it your expectation that because that was a part of the quarterly report, that FDA understood that Actiq would be used in off-label -- in an off-label manner?
A. I wouldn't say it that way.
Q. Is it your understanding because there was an off-label component to the quarterly report that the FDA understood that there may be off-label use by physicians of Actiq?
A. Yeah, I'm not sure that that's -- I mean, I think FDA was concerned about off-label from the beginning, independent of the quarterly reports. That's my only point.
Q. And you're not aware of any marketing that occurred of Actiq -- strike that.

Page 673

You're not aware of any marketing that Teva did of Actiq after 2006, correct?
A. No. Exactly the evidence in my report.
Q. Thank you. You are not issuing any opinion in this litigation related to the adequacy of the label for Actiq, are you?
A. Not -- not -- no. I think the answer to that question would be no. I would just want to reserve the ability to read the label.
I mean, I issue no opinion on that. We've discussed other inadequacies in general in information. So there may be a sentence here or there in the label that may be relevant to our conversation, but I've issued no opinion and will not issue an opinion that that label was inadequate.
Q. In your opinion section of your report regarding Actiq, you refer to internal marketing documents, and we've -- you've discussed at length with some of my co-defendants your ability to kind of interpret internal marketing plans.

Page 674

Do you recall that testimony?
A. Yes.
Q. Have you reviewed and relied upon any outward-facing external marketing documents that you believe failed to comply with the Actiq risk management obligation?
A. So I mean, I do have -- and I cite it -- I do have certainly call notes that are cited somewhere on reliance or not. Those are outwardly facing. And I think that -- I mean, they are pretty blatant when they come to off-label marketing. So I think the call notes are what come to mind --
Q. Did you --
A. -- right now.
Q. Did you review any marketing pieces or leave-behinds related to Actiq that were -- that were used by either detail reps or anyone at Teva that failed to comply with the risk management profile?
A. No. What I was able to find -- what I was able to find and focusing on were more the strategy documents, obviously the documents that came out of the criminal -- what

Page 675

of the enforcement action. And the actual interactions between sales reps and doctors.
Q. And the enforcement action that you're referring to, is that the 2008 plea agreement and the corporate integrity agreement in 2008?
A. Both, yes.
Q. Okay. And so we can agree that as you testified a few moments ago, that the actions that you are critical of related to Actiq all pre-dated certainly the enforcement action in 2008, but based on the documents you've reviewed, were 2006 or earlier, correct?
A. I think that's -- that's fair. Again, I think that would be fair.
Q. Do you know -- strike that.
Can you identify any physician in Summit or Cuyahoga County who was misled by any of the marketing of Actiq?
MR. RAFFERTY: Object to the form.
A. So sitting here today, I cannot specifically. I would need to -- I mean, I've searched the -- I have the call notes, and I'm not sure -- I didn't search specifically for

Page 676

Cuyahoga and Summit. I have dozens of call notes here. But I would have to go search these specifically for Cuyahoga and Summit and would be happy to do that --
Q. And in --
A. -- in order to answer your question.
Q. For purposes of your report, you didn't identify any specific physicians who, in 2006 or earlier, were misled by any marketing effort by Teva related to Actiq?
A. Well, I mean, we do -- we do have call notes where this -- which do have physician names and sales representative names, and that those certainly show the drug is being promoted for things like a migraine and low back pain.
Q. But, sir --
A. And those have names associated, and I can give you those names.
Q. Those notes are not notes from the physicians demonstrating that they were misled though, right?
A. You're correct, ma'am. Those are

Page 677

notes from -- well, those are representations by the sales rep.
Q. Can you identify any inappropriate or improper prescriptions of Actiq that were written in Cuyahoga or Summit County based on any statements made by Teva?
A. Sitting here --
MR. RAFFERTY: Object to the form.
A. Sitting here right now, I cannot. I would have to go back and -- I think the way we would do this is, I would look at the call notes specifically for Cuyahoga and Summit and see what the representations are as we discussed earlier, for example, of the doctors in those call notes and whether they said they would change. I don't have that evidence today.
Q. And how would you identify from the call note an improper prescription?
A. Well, when a call note as we saw before says, discussed -- for example, it says, discussed -- and I'm not saying this happened in Teva, we'd have to look at the call notes, but as I talked about earlier in certain call

Page 678

notes, if it says, Discussed chronic back pain, discussed migraine; doctor says, I'm going to prescribe for this; doctor says he or she is going to prescribe for this, again, that doesn't tell you what the actual outcome is. I understand that. But it takes you pretty close, and we saw that earlier.
Q. Isn't it true --
A. Can I just add one point to that? We do know -- we do have call notes outside of Cuyahoga and Summit, and we do have testimony that, in essence, what happened in Cuyahoga -- what happened nationally happened in Cuyahoga and Summit.
Q. But right now you can't point me to any improper prescriptions written in Summit or Cuyahoga County as a result of alleged improper marketing by Teva?
A. You're exactly correct. I'd have to search these call notes for that.
Q. And isn't it true, sir, to determine whether any prescription is improper, you would have to look at the circumstances surrounding that prescription, the information

Page 679

in that patient's file, the interaction with the physician, and actually talk with the physician?
A. You're conflating something again. It's late. Whether the promotion was off-label and resulted in a prescription, I mean, that you may or may not be able to determine from the call note.
I mean, obviously if the call note said, as we said, you know, discussed migraine and chronic back pain, and doctor says, I'm going to start prescribing for chronic back pain and migraine in that call note --
Q. My question is different. My question is not what the call notes show. My question is whether you can determine that a prescription is improper without looking at the patient's medical history, the patient's medical condition, and talking with the physician about that physician's decision to prescribe?
A. I'm sorry, I misunderstood.
With regard to improper prescribing, I think you're correct. With

Page 680

regard to improper promotion, I think -- and its effect on promotion, you can determine that from the documents.
Q. Sir, is it your opinion that any prescriptions written before 2006 for Actiq were improper?
A. All prescriptions for Actiq were improper before 2006?
Q. Right.
A. Could you just give me the label again? I mean, I'd like to see the label before I answer that question.
Q. Well, it's actually a question that I don't think you need to see the label. I asked, is it your opinion that any prescriptions written before 2006 -- so when you opined that this improper marketing was going on -- were any prescriptions written in that time period improper?
A. I need to see the --
MR. RAFFERTY: Object to the form.
A. I need to see the label.
Q. Why do you need to see the label to answer that?

Page 681

A. Because I want to see precisely what the limitations of use says, and that could inform me on -- you used the word "proper," and I just want to be precise.

So I'd want to -- in certain instances, FDA --

Q. Well, I don't --

A. -- for example, in Oralet, the predecessor, if you were using Oralet out of the constraints that we set for Oralet, so I just want to be precise and I just --

Q. Sir, respectfully, I don't have time to show you the label right now. My question is simple. Either yes or no, all of them were improper or all of them were not. And then we can go through and talk about the categories of those which you have opined are improper and those which are not.

MR. RAFFERTY: Okay. I'm going to state an objection. I think there's been some confusion, because I believe you've used the words "any" and "all" at different times, and so --

MS. FEINSTEIN: Thank you, Counsel.

Page 682

MR. RAFFERTY: -- I think, and if I could just -- two seconds -- and I think it's not yes or no, and I don't think it's appropriate to instruct the witness on how to answer the question. It could be that he can't answer the question without reviewing the documents, which he has a right to do.

MS. FEINSTEIN: Let me try again.

Q. So, sir, you've opined -- it's your opinion that Teva engaged in improper marketing of Actiq --

A. For off-label use.

Q. -- for off-label use before 2006, right?

A. Correct.

Q. In that time frame, you would agree with me that physicians could write off-label prescriptions, right?

MR. RAFFERTY: Object to the form, asked and answered.

A. Just give me one more second before I answer that question.

Q. And if you can just tell us for the record what you're referring to.

A. I'm looking at the various label changes and the black box warnings. So I'm just getting -- because unlike many drugs, this, as I remember, has certain admonitions to doctors. That's unusual. So there's an added level of scrutiny here with regard to Actiq.

Q. And you're referring to the schedule in your report that has sections -- excerpts of the label?

A. Yes.

Q. Okay.

A. So, for example, it says -- just so you know why I want to be careful, it says, Physicians and other health care providers must become familiar with the important warnings in this label.

Q. Right.

A. So that's -- it's very rare that there's an admonition that says, Physicians must become aware of that in a label.

Q. And so, sir, is it your opinion that all prescriptions written off-label for Actiq were improper?

Page 684

MS. FEINSTEIN: Can we go off the record while he's reviewing this? Let's go off the record.

VIDEO OPERATOR: 2:52, we are off the video record.

(A discussion was held off the record.)

VIDEO OPERATOR: 2:53, we are on the video record.

BY MS. FEINSTEIN:

Q. Can you answer my question now?

A. I don't want to -- my opinion, and I don't want to give a legal opinion, so I'll use a little L, you know, I don't think it is unlawful or violative, and again, I don't want to get -- for a physician to prescribe off-label. There are two -- but there is a --

Q. Okay. Well, that answers my question, sir, and we're really tight on time, and I don't mean to cut you off.

A. I understand, but there are two things in this label that are unique when it says it's indicated only --

Q. Thank you.

Page 685

A. -- and physicians must -- it would go towards that question.
Q. Thank you. Thank you, and I don't mean to rush you. We're just all very tight.
A. I understand.
Q. So I'd like to now move to Fentora and your opinions about Fentora which follow -- there's just one opinion actually regarding Fentora in your report. And it --
A. Just give me the paragraph, please.
Q. Sure. The opinions start in paragraph 483, which is on 260, and continue to 493, which is on page 262 of Exhibit 1, which is your report.
A. Right.
Q. And paragraph 493 reads, In my opinion, Teva promoted Fentora for non-malignant pain, which lacks substantial evidence to support safety.
Correct?
A. Correct.
Q. It appears to me, based on the materials --
A. Sorry, that -- you read that,

Page 686

that's paragraph -- I'm blocking. What paragraph did you just read?
Q. 493.
A. 493, I'm sorry. I just haven't finished -- yes, ma'am.
Q. Sure. It appears to me from looking at your report that the materials you relied on in reaching that opinion relate to actions from 2008 forward. Is that right?
A. You know, I'm looking at the 2005 marketing plan in front of me, so I'd have to look at -- in fact, that's cited in here also on 489, the 2005 marketing plan.
Q. So 2008, it appears to me that from 2008 -- I'm sorry, I misspoke.
2008 back, so anything from 2008 to earlier is the activity that you're critical of with respect to Fentora; is that right?
A. That's the evidence. That and anything in my reliance list would support the evidence to this, yes.
Q. Do you have any opinion that Fentora was improperly marketed by Teva in 2009 or forward?

Page 687

A. I think you can trust my sense to -- what's in the report is the evidence that I have. I'd want to double-check my reliance list, but my guess is that it will be what's in the report.
I also have a sheet in front of me if you want to take a look. I don't think -- I'd have to check the dates of these documents, but during that --
Q. I'm sorry. And that those are internal documents, you referred to again some internal marketing documents in the body of your report, right?
A. Yes. So yes. Well, I mean, body or reliance list. I apologize, I'm not sure. They're on my list.
Q. The document that you are looking at right now is in your big packet that we are going to mark. These are your kind of working set of materials, and it's clipped with a binder clip, and we're going to mark that as an exhibit following the deposition, right?
A. Fine.
Q. But that's what you're looking at,

Page 688

for clarity?
A. Exactly. Take this report, take this page, and I think you can feel comfortable that that's the -- that's what supports my opinion.
Q. Perfect. Thank you. That was going to be my question, so I appreciate that.
Doctor, you're not aware of any marketing statements made by Teva in Cuyahoga or Summit County, specific marketing statements that were false or misleading, are you?
MR. RAFFERTY: Object to the form.
A. I think the answer to that would be no, but the campaigns and the testimony is there was -- this was national in scope on break-through pain. So there's no reason to think that -- or there's no evidence to say it was any different there.
Q. And sitting here today, Doctor, same question that I asked you a few moments ago regarding Actiq, can you identify any providers in Cuyahoga or Summit County who were misled by any statements by Teva related to Fentora?

Page 689

MR. RAFFERTY: Object to the form.
A. Sitting here right now, I cannot.
Q. Can you identify any inappropriate or improper prescriptions of Fentora that were written in Cuyahoga or Summit County based on false statements made by Teva?
MR. RAFFERTY: Object to the form.
A. I do have -- you can look at these documents, and these are based on recall of messages, and we'd have to dig down and see where exactly these -- this recall was done in this document to answer your question fully.
Because this clearly tells you what the impact the recall was of those messages that were off-label, and we see that -- again, I think this was done nationally, and we'd have to look -- again, this was nationally marketed. So I'd just have to look -- we'd have to look at the calls that were made.
Q. You can't identify any inappropriate or improper prescriptions, sitting here today right now, that were written for Fentora in Cuyahoga or Summit County based on false statements made by Teva?

Page 690

MR. RAFFERTY: Object to the form.
A. You're talking about the prescriptions itself --
Q. Yeah.
A. -- or the calls itself?
Q. The prescriptions.
A. Of Fentora? No, I cannot. I can talk about -- I mean, I can talk about overall physician national recall. That's all I can do.
Q. Your report also refers to certain funding provided by Teva to a couple of organizations.
A. Do me a favor. Can I just get -- I just need to switch my documents out. Do you want to go off the record for a second?
MS. FEINSTEIN: Sure.
THE WITNESS: Just go off the record. Preserve your time.
VIDEO OPERATOR: 2:59, we are off the video record.
(A discussion was held off the record.)
VIDEO OPERATOR: 3:02, we are on

Page 691

the video record.
BY MS. FEINSTEIN:
Q. Doctor, I'd like to refer you to paragraph 582.4 of your report, which is Exhibit 1.
That paragraph refers to payments made by Teva to the American --
A. 582 point --
Q. 4.
A. Yes.
Q. -- payments made by Teva to the American Pain Society over the time period 2009 to 2013 --
A. Correct.
Q. -- in the amount of $218,000, correct?
A. Correct.
Q. Is it your opinion, sir, that those payments were inappropriate or improper?
A. I think they contributed to the overall view of opioids. I don't think that they were illegal, but I think they contributed to the overview of opioids.
Q. Do you know whether any of those

Page 692

payments were made as a part of any risk management obligations on the part of the company?
A. I need to open my notebook, and I don't want to do that under the time constraints.
So I'd be happy -- so the answer is, sitting here, I'd have to check that question.
Q. If payments were made as a part of a risk management program, would that change your view of whether those were appropriate payments or not?
A. Not if the risk management program was misleading. And as we know from the record, risk management programs did talk about pseudoaddiction or less addictive risk. So that, again, contributed to this change in culture, so that's part of the problem.
Q. Referring you now to paragraph 610.3 of your report --
A. Is there rule that once we get to the 600s, we can't go backwards?
Q. No, unfortunately.

Page 693

So this paragraph refers to a contribution by Teva in the amount of $130,000 to the Federation of State Medical Boards.

Do you see that?

A. Yes.

Q. And you referred to this as a grant to support the distribution of responsible opioid prescribing, correct?

A. Yes.

Q. Is it your opinion, sir, that that payment was improper?

A. I don't think it's illegal, but I think if you go to paragraph 611, you see that those statements that came out of that organization were misleading.

So I wouldn't want to say that money was illegal, but it did contribute to that change in understanding of opioids, which was misleading.

Q. But the payment itself was not improper?

A. Well, I used the word "illegal." I mean, I think it -- it certainly -- it would have been better not to contribute to these

Page 694

organizations that misled the public.

Q. And you didn't review any of the underlying agreements or contracts related to either of those payments with Teva and those organizations, right?

A. I may have. I have to go back and look at the reliance list.

Q. Sir, just a couple of other quick questions, and then I've got to pass the baton.

You are not providing -- strike that.

You're aware of the TIRF REMS program?

A. Yes.

Q. You know that that program applies to Fentora and Actiq, right?

A. Absolutely.

And a lot of controversy about that program.

Q. Are you -- you're not rendering any opinion in this litigation about TIRF REMS, are you?

A. Other than they are inadequate. I think you can stop there.

Page 695

Q. You have not provided any opinion regarding Teva's compliance with TIRF REMS, have you?

A. Only what's -- only within the report. They're certainly inadequate to do the job. I think that would be my only --

Q. It's your view that the TIRF REMS program is inadequate to do its job; is that right?

A. I think the record is pretty clear on that and the recent advisory committees and testimony.

Q. But you don't have an opinion in your report, Exhibit 1, about TIRF REMS and Teva's products?

A. You asked me a question, and I gave you an answer. I mean, I -- but I -- I mean, that's why I answered it. But I'm not going to disagree with you. I mean -- I mean, what's in the report is in the report.

Q. Sir, are there any opinions that you hold regarding Teva that are not in your report but that you plan to testify about at trial?

Page 696

A. I would only -- anything -- if you can change your question to include anything in the report and what we just discussed today, I would say I have no intent to go beyond what we talked about today and what's in the report.

MS. FEINSTEIN: Excellent. Thank you, sir.

With that, I am just going to note on the record -- I am going to pass the witness, but I will note on the record Teva's objection to the amount of time that all defendants collectively were allowed to conduct this deposition that -- regarding an expert who rendered extensive opinions about many companies, and sharing this limited time is inadequate, from our opinion.

So with that, thank you, Doctor. Appreciate it, and we'll go off the record.

MR. RAFFERTY: Wait, wait.

Plaintiffs continue to disagree.

VIDEO OPERATOR: 3:08, we are off the video record.

Page 697

(Recess from 3:08 p.m. until 3:25 p.m.)
(Exhibits Kessler-25 through Kessler-39 marked for identification and attached to the transcript.)
VIDEO OPERATOR: 3:25, we are on the video record.
EXAMINATION
BY MS. LEVY:
Q. Good afternoon, Dr. Kessler. My name is Jennifer Levy, and I am counsel for the Allergan defendants in this case. I appreciate your patience in hanging with all of us over this two-day period. I really do.
I would like to pick up with where -- the questioning just before the break that counsel for Teva had asked you with respect to your opinions on what prescriptions were tainted by unlawful marketing and what prescriptions weren't, and I would like to ask you specifically with respect to the opioid Kadian.
If I represent to you, Dr. Kessler, that there were 14,908 Kadian prescriptions in

Page 698

Cuyahoga and Summit County over the period of time that that product has been on my client's watch, you would agree with me that some portion of those prescriptions were legitimate prescriptions for patients who needed the product, correct?
A. I think that would be fair.
Q. And in your view, to the extent there were any physicians that prescribed some of those 14,908 prescriptions who were misled by improper marketing, those prescriptions would not be appropriate prescriptions, in your view; is that correct?
A. If they were misled -- and we had, you know, an extended back-and-forth; is there any possibility that they would be still appropriate, because they weren't misled. But once they were misled, it comes pretty close.
So I think that's a fair -- we had this discussion a little while earlier, and I stand by that, I think is probably the best way to say it.
Q. It's possible -- it's possible, I suppose, for a prescriber to be misled for a

Page 699

period of time and then unmisled. Do you agree that that's a possibility?
A. Yeah, that's -- in essence, those are the kinds of things that I was referring to.
Q. Okay.
A. That was --
Q. So in order to tell --
I'm sorry. I did not mean to cut you off.
In order to tell if a prescription in a particular jurisdiction is legitimate, you would need to know if the prescriber was misled or if the prescriber wasn't misled, right?
MR. RAFFERTY: Object to the form.
A. I think there's a number of methodologies that I talked about over the last day and a half that --
If there's an ROI that has been calculated on certain promotional activities and you know those promotional activities had misleading -- and you know what increased number of prescriptions that promotional activity led to, I think that's one methodology

Page 700

that we talked about.
Obviously, there are others, as you're alluding to.
Q. I think I understand you to say, if there is evidence that a particular misleading promotional activity is linked directly to an increase in prescribing, you can assume that that increase is -- results in prescriptions that are not legitimate and lawful. Correct?
A. "Lawful" -- take "lawful" out because -- but it would be inappropriate -- it would be -- it would be a contribution of inappropriate prescribing.
Q. Okay. And you haven't made any attempt to quantify for the opioid Kadian what percentage of the prescriptions in Cuyahoga and Summit County were lawful versus unlawful or legitimate versus illegitimate? You haven't made an attempt to do that, have you?
MR. RAFFERTY: Object to the form.
A. Correct.
Q. And you haven't made an attempt to do that for any of the opioids that are the subject of your report. You haven't made an

Page 701

attempt to quantify percentages of -- what percent were legitimate prescriptions and what percent weren't. That's not -- you haven't done any of that, have you?

A. I've not done --

MR. RAFFERTY: Object to the form.

A. I don't think that's exactly my testimony here over the last day and a half. I think there were documents -- happy to pull them, again -- that show what the ROI was with regard to other manufacturers. I don't see that with regard to documents I've seen in Kadian. I don't have those ROI documents that I'm aware of from Kadian.

Q. And your report addresses Actavis and Kadian on pages 263 through 276; is that right?

A. Yes.

Q. Okay. And are those the only opinions that you intend to offer in the trial of this case with respect to Actavis?

A. If you stopped right now and you passed the baton, the answer to that question would be yes.

Page 702

If you ask me other questions, you know, I may give you certain opinions based on what you ask me. But my intent right now would be to stop right here.

Q. Okay. That's fair.

So if I'm understanding you correctly, the opinions in that section of your report plus whatever we talk about today are the opinions that you intend to give at trial with respect to Actavis; is that right?

A. Well said, Counselor.

Q. And I take it, by extension, that you don't intend to offer any opinions with respect to products that Actavis may have marketed or sold that are not addressed in your report; is that correct?

A. So the only -- the only caveat to that, Counselor, is one that I think I made early in the day twice, both to Mallinckrodt and I believe to Teva, is, we know Actavis sold -- its predecessors sold oxycodone ER for a period of time in a generic form, I believe, and to the extent that the general statement about the manufacturers contributing to

Page 703

increasing that water level, as I testified, would apply to both the generics and the brand.

Q. So let's talk -- I'm going to place-hold that to talk more about in a moment.

But with that exception, other than that exception, you don't have any other products or opinions aside from what we talk about today that you intend to testify about at trial; is that correct?

A. Correct.

Q. Okay. Now, let's do some marking. We put a sticker on your pile in front of you. And can you do me a favor and tell me what exhibit number that is.

A. 36, ma'am.

Q. What is Exhibit 36?

A. 36 was simply, I asked -- what this -- what this whole thing is?

Q. Yes.

A. Sort of my brain on paper.

Q. So let me see if you would agree with my characterization.

Is this your file as it relates to Actavis?

Page 704

A. Well, there's binders. There's bigger sheets than even these. There's -- so there's a number of different things here. But I am -- if you'll -- it's not the entire file, but I think maybe it's -- it represents documents that I've cut and pasted or notes or markings that I have made over a period of time and inartfully -- and tried to tape onto paper or write onto paper.

Q. Give me just one minute.

Okay, Dr. Kessler. Exhibit 36, which looks to me to be your notes and some important documents that you've pulled out in your opinion with respect to Actavis.

Is that a fair characterization?

A. Yes, ma'am.

Q. Okay. In addition to that, you have another extremely large document in front of you that is marked Exhibit what?

A. 39.

Q. What is Exhibit 39?

A. So 39 is just a visual, in essence, of the paragraphs in my report that I attempted to put together by categories.

Page 705

So it talks about low abuse potential, less addiction, pseudoaddiction, overstatement of benefits, overstatement of other benefits. So it uses those headings as they apply to all the manufacturers, and then these are just simply the paragraphs under the report under those headings.

So it's an attempt to see things visually that I may not -- all in one sheet that just -- you know, it's just a visual mapping.

Q. It's how you organize the evidence that you've found for particular defendants?

A. It was a way of looking -- trying to understand -- trying to see things in just -- see things in a little different -- in different categories.

Q. In addition to 36 and 39, I have in front of me two binders that are labeled Number 9, Actavis, both of them, and they have different paragraph numbers. We've marked these as Exhibit 37 and 38.

Are you familiar with these?

A. I'm very familiar with those.

Page 706

Q. These are the documents in your reliance materials that relate to Actavis, correct?

A. No.

Q. What are these?

A. So those are the documents that are cited in -- so if you turn to a paragraph, you'll see a paragraph number, and that corresponds to this paragraph. And if there's a footnote, it is a cite from that paragraph, that cite would be in that paragraph. And if there's a quote, that's what the flags are that you see sticking out are the quotes.

But that doesn't necessarily -- these don't print out everything on the reliance list.

Q. So this is an appendix, essentially, to your report, everything cited in your report?

A. I've given you an appendix. I've given you schedules. I would hate to call it an appendix because I hope I don't have to carry these around for the rest of my life. So I wouldn't give them any more official status

Page 707

other than wanting to have these documents available.

As you saw me earlier, people asked me about a question about a paragraph, and I wanted not to just to read my report, but wanted to see the document that was cited in that. So I opened those binders. That's the purpose.

Q. If I wanted to know the entire universe of your reliance materials that relate to Actavis, I would need to have the documents that are in the big chart that is marked as Exhibit 39, the pile in front of you that's marked as Exhibit 36, these two documents, 37 and 38, and what else?

MR. RAFFERTY: Object to the form.

Go ahead. I won't interfere.

A. You would need to take the reliance list, create PDFs of the reliance -- have PDFs of the reliance list and -- what was your question? With regard to Actavis? Is that what you specifically -- you would probably have to search the reliance list in addition to these documents.

Page 708

Q. And did you read everything in all of these binders?

A. I'm not going to -- I don't mean to be facetious. Define "read."

Q. Lay your eyes on it, just lay your eyes on everything in the binders, just start with that.

A. I laid my eyes on a lot of things, yes. I'm not sure that I've studied every -- I certainly have not studied every page, but I certainly have laid my eyes on a lot of these pages, but I don't want to represent that every page got the same kind of -- every word got read.

Q. Okay. I want to talk to you more about those documents, but for a minute, I want to go back to your report and start with something I read in paragraph 6 where you state, I am a senior advisor to TPG Capital, a leading global private equity firm which owns pharmaceutical and biomedical companies.

Do you recall that in your report?

A. Yes, ma'am.

Q. Are you paid by TPG to be a senior

Page 709

advisor?
A. Yes.
Q. How are you paid?
A. Well, really two ways. I think there's some retainer that's relatively small, and then there are TPG companies that I sit on the boards of. And those companies -- by sitting on the boards, I'm paid by those companies.
Q. Do you have stock in TPG?
A. No.
Q. And do you have stock in any of the companies in TPG?
A. I have stock in the companies that are owned, yes. I believe that's correct. Those are privately held shares.
Q. Okay. One of the companies that TPG owns is Collegium; is that correct?
A. Not a company that I've worked on.
Q. You don't know, one way or the other, whether --
A. Sorry. I don't --
Q. -- TPG owns Collegium?
A. I know the ones I've worked on. I

Page 710

don't know that.
Q. I'm not asking if you've worked on it. I just want to know if you know whether TPG owns Collegium.
A. I don't.
(Exhibit Kessler-40 marked for identification and attached to the transcript.)
BY MS. LEVY:
Q. I'm going to show you what I've just marked as Kessler Exhibit 40.
I'll ask you, Dr. Kessler, if you've seen this document before or are familiar with its contents.
A. Sitting here today, I have no recollection of this. I don't -- I don't believe I've seen this document.
Q. Okay. No one's ever told you that Collegium Pharmaceuticals received this warning letter from the FDA?
A. No. I'm not involved. Absolutely not.
Q. That's new news to you?
A. Absolutely. I'm not involved.

Page 711

Never seen this before.
Q. Does the fact that a company gets a warning letter, does that automatically mean the company has done something wrong?
A. Pretty much. I mean -- well, let's look at the warning letter.
Q. Before we look at that one, I mean, in general. If you know a company got a warning letter, can you be sure that it did something wrong, in your opinion?
A. Ma'am --
MR. RAFFERTY: Object to the form.
A. As you know, there's warning letters, and there's warning letters. And I would want to -- there are warning letters that say that there's -- FDA considers it a violation of the act and will cite a specific statutory section, and that -- so that, I think, gives you -- depends what the letter says is the answer.
Q. Fair point.
I bet you will agree with me that the FDA keeps enforcement statistics on its website.

Page 712

You're familiar with that, right?
A. I am.
Q. And, in fact, you can click on the FDA website and see summaries by year of those FDA statistics, correct?
A. Yeah.
(Exhibit Kessler-41 marked for identification and attached to the transcript.)
BY MS. LEVY:
Q. I'm going to show you what's been marked as Kessler Exhibit 41.
I will represent to you, Dr. Kessler, that this is a chart that we copied from the FDA website or pulled substantively from the FDA website.
Are you familiar with statistics that look like this from the FDA website?
A. In general, yes.
Q. Under the Kessler FDA, were statistics like this kept?
A. I assume so. I can't visualize them, as I sit here. But I think that's fair. I think it's a practice that goes back decades.

Page 713

Q. The left-hand column of Exhibit 41 says Enforcement Type, and the right-hand column says Count.

Do you see that?

A. I do.

Q. I will represent to you that we pulled Exhibit 41 for 2017.

Will you agree with me, Dr. Kessler, that the actions on the left-hand side under Enforcement Type, these are actions that the FDA can take or cause to be taken directly or indirectly, correct?

A. I assume you're referring to injunctions and going into court, et cetera. Is that what you mean by "indirectly"?

Q. Mm-hmm.

A. Yeah. I think if we understand that, I think that's -- there are steps to each -- different steps to each one of these. Some of these, for example, recalled are -- they may be voluntary recalls. So be careful on whether FDA took that step or the manufacturer took that step. So there's nuances to these.

Page 714

Q. And that's why I said "directly or indirectly."

These are things that can happen when the FDA sees a problem, right?

A. Or when a manufacturer sees a problem, they can do a recall. I'm not sure we would say that all recall products are -- I mean, they get reported ultimately -- should get reported to the FDA. The manufacturer may see them first.

Q. Assuming that I represent to you that I copied these correctly from the FDA website, you understand the count on the right-hand side to be the number of times that the FDA took such an action in 2017? Is that how you would read that?

MR. RAFFERTY: I'm going to object just because I don't know where -- I haven't had a chance to corroborate where it came from. So I'm just going to object since there's no FDA cite or anything --

MS. LEVY: Sure. That's exactly why I asked the question the way I did.

Page 715

A. You're asking me -- I'm sorry. The question was --

Q. What does the count mean on the right-hand side?

A. I would think the number of actions under each. It's a lot of warning letters, but I'm not -- you know, I'm sure you took it off right. 15,000 warning letters seems like a lot of warning letters in one year.

I'm not sure -- I'm sure you did this accurately, and I'll take any representations you make, Counselor.

Q. In your own experience, warning letters are a common thing that the FDA does, correct?

A. Common, you know, I mean, they are -- they are something that the FDA does.

Q. Okay. And recalled products are also common. Here we see in 2017, there's -- 9,199 is the count for recalled products, and 2,945 is recall events.

Do you see that?

A. Yeah. Yes, I see this.

Q. It's not uncommon to have recalled

Page 716

products and recall events, is it?

MR. RAFFERTY: Object to the form in terms of not defining what "products" or "events" are.

Q. You can answer.

A. I would phrase it, it's not unusual. You've got to look at the denominator to see what's common here. It's not unusual to see recalled products.

MR. RAFFERTY: What exhibit was that?

THE WITNESS: 41.

Q. I have in front of you -- I think I marked the Collegium warning letter at -- as Exhibit 40.

Can you pull that one back up.

A. Yeah.

Q. Is Collegium a drug company that you believe has contributed to the opioid crisis?

A. I have not, you know -- there may be one or two issues over, I don't know, the last -- since 2008 that -- where I may have discussed with colleagues ADT formulation or

Page 717

something like that, as I think I talked about earlier.

But save for that, I have no -- I've not studied Collegium. I'm happy to do that, if you'd like. I just -- I have -- but for those two conversations, really one on ADT -- the one conversation I remember on an ADT product, I have no knowledge of anything about this. I don't know who Mr. West is. I'm just not involved with it.

Q. For purposes of this litigation, you have not been asked to study Collegium's responsibility, have you?

A. It was not one of the manufacturers -- is it a defendant? I wasn't -- maybe it's on my list. I don't know if it's on my list. I listed all the defendants. It's in my report.

But I was asked specifically to -- by plaintiffs -- they gave they the scope. They gave me the list. I didn't change that in any way.

Q. Got it.

So what you did for purposes of

Page 718

this litigation was to study the defendants that are the subject of your report, and that's it?

A. If you look at the beginning of the report in the first section, I think the last several paragraphs or paragraph on just scope, I asked specifically for what the scope was, and I addressed myself, after it was determined what the scope was, to those question.

Q. Did you make any effort to determine how many other drug companies had conduct that contributed to the concerns you have about opioids?

MR. RAFFERTY: Object to the form.

A. I will tell you that I was sort of exhausted after just doing these, to be honest, right. I mean, this is -- the scope that was given to me is vast.

I will tell you that in -- I mean, I did study the database broadly.

Q. What database?

A. Well, the production database. Okay.

Q. By "the production database," you

Page 719

mean the documents produced in this case?

A. Yes.

Q. By these defendants?

A. Well, again, there were third parties, et cetera. I mean, don't ask me to define -- I mean, the database are the defendants.

So I did look at that -- that sort of broadly. But there are other drugs that we talked about earlier where I didn't spend a lot of time because they were not the subject.

I mean, my impression and my sense was that the major drugs that contributed to the epidemic were drugs that are identified in the report. That was my impression, and that's my sense.

Q. But you didn't do anything to see if that was true? You didn't look at any other drug companies other than the ones that are in the seven in your report? You didn't look at -- I'm sorry -- the six in your report?

MR. RAFFERTY: Object to the form.

Q. You either did or you didn't. You examined the six in your report, and you

Page 720

studied those until you were complete with that?

A. I did.

Q. But did you study any others --

A. Yes, I did.

Q. -- other than the six?

MR. RAFFERTY: Object to the form.

Q. Just name -- without going into what you did, name the other drug companies that you studied.

A. Abbott.

Q. Who else besides Abbott did you study?

A. Abbott's the one that comes to mind.

Q. Is that the only one?

A. I'd have to go back and look. That's the one that comes to mind.

Q. When you studied Abbott's conduct, did you conclude that Abbott had responsibility for the opioid crisis?

A. I think so.

Q. Okay.

A. I mean, it -- so the record is

Page 721

clear, I mean, it was basically -- it co-promoted oxycodone with Purdue. So there was a joint licensing agreement. So I think it's fair to say that those marketing plans of Purdue carried over to Abbott. It was a joint venture of sorts.

Q. Now, you mentioned, I believe, earlier that you did not study Collegium, right?

A. No. I'm not sure that -- no, the answer is, I did not.

Q. Okay. And as you sit here today, do you have an opinion on whether Collegium contributed to the opioid crisis?

MR. RAFFERTY: Object to the form.

Q. It's a yes, no, or I don't know.

A. I haven't studied it. So I can tell you I have no opinion.

Q. Okay. And how many total drug manufacturers are there that manufactured and marketed opioids in this country?

A. I have documents on market share that I'd be happy --

Q. Roughly. What's the rough number

Page 722

of companies?

A. I'd want to look at the charts that I have before I give you an answer.

Q. Do you know if it's dozens?

A. I have -- I have the market share. There are -- I wouldn't want to hazard a guess at this time. I do have the documents. If you want me to look at them, I'd be happy to give you the numbers.

Q. We may want to do that, but for the moment, you'll agree with me that there are many, many drug manufacturers that you did not study to determine whether they had responsibility for the opioid crisis. Is that fair?

MR. RAFFERTY: Object to the form.

A. No. I think it's fair to say that I studied the major -- without a doubt, the major brand name companies.

Q. And how did you determine the major brand name companies, or did you just study what you were asked to study by counsel?

A. No. If you look at those market shares and you look at certainly the extended

Page 723

release and you look at the competitors, it's very easy -- when you look at Purdue's market plans, they talk about who the competitors are. I showed, for example, the Mallinckrodt graph yesterday that showed the Purdue market share.

So you can quite easily, based on the record, see what the percent market shares are and who's competing against whom. Purdue was competing against Kadian early on. You see that in the documents.

Q. Are you finished?

MS. FREIWALD: Objection, move to strike. It mischaracterizes the facts in this case.

BY MS. LEVY:

Q. I'm going to ask a pretty simple question.

You've identified six manufacturers in your report, and today you've identified Abbott.

Is there any other drug company whose conduct you studied to determine if they had contribution for the opioid crisis? Any others other than those seven?

Page 724

A. Yes.

Q. What other company?

A. Well, I think I talked about -- well, I talked about Rhodes.

Q. Okay. And did you conclude that Rhodes does or does not have responsibility for the opioid crisis?

A. I think Rhodes is owned by Purdue. I think the answer is complicated.

Q. You can't say one way or the other?

MR. RAFFERTY: Object to the form.

A. Well, Rhodes is -- Rhodes, at different times, is making API. Noramco is making bulk. Tasmanian Alkaloids. I've studied all those.

They certainly feed in, right, to the -- without Tasmanian Alkaloids, but for, you wouldn't have supply the way we had supply.

So again, I think it's fair to say it's complicated, and I studied those, yes.

Q. Let's talk about drug companies that have no affiliation with any defendant in this room.

How many of those did you study,

Page 725

aside from Abbott, to determine if they had contribution for the opioid crisis? Just a number. How many?
A. I studied -- well, there's Abbott.
Q. Just a number.
A. Without any affiliation?
Q. Without affiliation to these defendants.
A. So Abbott has an affiliation -- I just want to understand your question -- to Purdue. Is that your question?
Q. Without any affiliation, is my question.
Let me redo the question --
A. How are you defining "affiliation"?
Q. -- just so we're clear.
MR. RAFFERTY: He can ask an explanation of the question if he doesn't understand it, Counsel, and that's what he was doing.
Q. Here's the question. How many drug companies with no affiliation to defendants in this room did you study aside from Abbott to determine if they had contribution for the

Page 726

opioid crisis? How many? Just the number.
A. So I've looked at data -- for example, for Amneal, Mylan, Qualitest, Roxane, Sandoz, Watson -- which, I guess, is, you know, related to you, so I take that back -- Rhodes -- when you look at the contributions on the generic side.
So, I mean, I've looked at -- I've looked at the market share and how those are spread out, and I've tried to study somewhat the flow between -- from the raw materials in the poppy fields to the API manufacturer to the brand to the generics.
This is all very highly interconnected, because, I mean, for example, Rhodes is on my list, but Rhodes -- rather, Watson, are connected to you.
So I think that the fact is, I am very comfortable that the manufacturers identified in the report did the bulk of the -- the vast, vast, vast majority of the promotion.
And I think it's basically shown when you look at the competitive landscape and the documents, again, in the record. The

Page 727

competitive landscape is such that the defendants that were identified make me comfortable that it's the bulk of the promotion that is happening.
Q. So those other drug companies that you just named are not responsible in any way for the opioid situation we're in? Is that your -- are they responsible or not responsible? Which is it?
MR. RAFFERTY: Object to the form.
A. So --
Q. I'd like to ask you, before you answer, to give me a short answer to this question.
The drug companies you referenced in your last answer, are they -- do they have responsibility, have no responsibility, or somewhere in between?
MR. RAFFERTY: If you can --
Q. I don't need an explanation.
MR. RAFFERTY: If you can answer the question the way she's directing you to, which is inappropriate -- if you can answer it, then you can answer it. But

Page 728

you don't need to be instructed to what your options are.
A. I don't see the record -- I mean, in the record, in what I've looked, I don't see the extent of the change in medical practice by these companies that were effected by the evidence in this report.
Q. And you -- I think in your last answer, you said, "the vast, vast, vast majority of promotion" was done by the defendants in this case.
Have you studied the quantity of promotion? Have you studied the number or the -- number of details or the quantity of promotion?
A. Oh, yeah. I mean, I have looked at sales force volumes. I have looked at, I mean, a whole lost of statistics. There's a Schedule, I think, 8 that has the promotional details. So I have looked at that, yes.
Q. And what percentage of promotion is the vast, vast majority? What percentage is that?
A. I don't have -- I'd want to add it

Page 729

up to give you a precise number. I wouldn't want to be precise right now.
Q. Okay. So for my client, Actavis, what percentage of the promotion do you assign to my client?
A. So I didn't -- as I said, I don't want to give a percentage. I think that at the peak, you had 50 sales reps, if my numbers are right. I'd want to check. Others, I think -- you know, again, I'd want to -- I haven't given a precise number, but I think that can give you a sense of -- sense of the scope of --
Q. So I'm not really interested in just a commentary as to what you learned about what we did.
I really want to know the methodology that you used to determine the amount of promotion per defendant. So what process did you go through to make your determinations about that?
A. I don't think the report gives you an exact quantitative aspect. It doesn't allocate responsibility between those defendants.

Page 730

If you'd like, I'd be happy to give -- if you define "responsibility" for me, I'd be happy to give you my opinion, but I didn't give a precise quantitative aspect.
Q. So what I really want is the opinions you're going to give at trial. At some other time, we can talk about your other opinions, because I do find that interesting, too. But I'm interested in the opinions that you plan to give at trial.
Do you plan to give at trial opinions quantifying the amount of promotion done by any particular defendant?
A. To the extent that that information is in my report and in my schedules, I'm happy to testify. There are dollar numbers and sales numbers and promotional numbers that are identified in my report, and I'd be happy to give you opinions based on those facts, right. But I'm not going to -- I don't intend to go outside of the report.
Q. So the things that would matter to you in determining the impact of a particular drug company's promotion, some of the things

Page 731

that you would consider would be the number of representatives. That matters to you, doesn't it?
A. Sure.
Q. And it matters to you the type of interaction that the representatives were having with prescribers. That would be relevant to your opinion, right?
A. Well --
Q. The content of what was being said.
A. Well said.
I mean, it's -- I mean, as you see, the report talks about the corporate messaging. It doesn't rely on just the numbers, but it's the corporate messaging.
I mean, again, the range of activities in promotion, I can probably -- in one of these charts, you'll see, you know, probably a list of 16, 17 highly sophisticated methods to influence doctors -- KOLs, KOL mapping, E-detailing, KOL channels -- each one measured, each one having -- looking for the return. So that there's not just one factor that goes into it.

Page 732

That's why the report tries to look at the -- I mean, the range of promotional activities. It's not just this individual detail.
Q. It matters also when in time the promotional activity occurred. That's also relevant to your views, isn't it?
A. Yes, I think -- I think that's fair.
I think we talked earlier about the initial sort of -- the initial promotion by Purdue, the -- what was -- you see what was going on with Kadian in the late '90s, early 2000s with Purdue, and then you certainly see other companies jumping in, trying to compete and expand the market after that time period.
So I do think there are different stages of this, so I do think timing is important.
Q. You've a couple times in this deposition talked about a shift in prescribing practices, and earlier in your deposition, you said, at some time after the 1980s, there was a shift in prescribing practices.

Page 733

Can you be more specific about when that shift occurred?
A. Yeah. Well, I can give you time points.
Q. Sure.
A. Okay? So if you look at the -- sort of the state of medical practice, okay, on oxy --
Q. For the record, can you put a sticker on that book that you're looking at, please?
A. Do I get it back?
Q. Yeah, just -- and we can say for the record the pages that you're referring to so we don't have to copy the whole book.
A. So, I mean, this is --
Q. What page number are you referring to?
(Exhibit Kessler-42 marked for identification and attached to the transcript.)
(Reporter interruption.)
MS. LEVY: I'm sorry.
BY MS. LEVY:

Page 734

Q. That is Exhibit 43 [sic]. It is marking a book in front of Dr. Kessler that is entitled what, sir?
A. 1980 Drugs of Choice 1981. I guess between 1980 and 1981.
It's -- actually, the title page is Drugs of Choice 1980-1981, Walter -- Dr. Walter Modell.
Q. So my question to you is, when -- when, just an answer in years -- did the shift in prescribing practices that you've described in your deposition -- when did that occur?
A. So, I mean, I think that the shift, as this book talks about -- it says that, We find that the risk of addiction greater than that -- and it's talking about oxycodone, for example -- We find the risk of addiction greater than that attributed to morphine...
And it ends up, Oxycodone is best considered as an orally-active morphine and should not be dispensed as freely as if it were a codeine.
And it concludes, Oxycodone, although useful, cannot be recommended as a

Page 735

drug of choice.
And so I think that was generally the practice in the 1980s, and I think -- I think in these documents and in market share, you can see the very -- the rise in the number of prescriptions over time, both with OxyContin and Duragesic and that that increase, which is pretty dramatic -- I guess between 1998 and 1999 is where it starts, and you can see it for, I mean, other trends.
So you have to plot the trend data, but I think that this sort of long-acting opioids or, certainly, the extended-release opioids, you see that there is -- I guess from 1998 to 2004 -- and this is not a full year, but you see this -- the market increased.
So I think the fact is, I'm going even earlier, 1980s. I mean, this stuff was not viewed as drugs of choice, more addictive than morphine.
And then this continues to take off, and you -- I have charts elsewhere that go even further. And as our share of voice increases, as this promotion increases, these

Page 736

drugs -- Opana ER does as well, for example.
So what you see is just graphic, but I think the answer is the -- that sort of tipping point, probably around '99, 2001, but continued to grow.
Q. So let me see if I can do this from across the table, and if I can't, I may come sit beside you.
But I want the record to be clear about what you're looking at, so let's mark for the record another one of your --
A. It's already marked.
MR. RAFFERTY: It's already marked.
MS. LEVY: Oh.
Q. Kessler Number 33, which has the marking that you put on it, Market Share, this is your market share pile? Is that a fair way to call it? This is your market share module? How do you -- how do you refer to it?
A. There's some market share. There's other market share in the report and the reliance list, but these are just some of the cut-and-paste. I don't want to represent these are the only ones. There are many documents

Page 737

cited in the report.
Q. I would like to give Exhibit 33 a name, so what do you want to call it?
A. Let's call it market share.
Q. Okay. So --
A. Market share papers.
Q. Your market share papers, as reflected in Exhibit 33 --
I believe when you gave your testimony -- I'm going to turn, if you don't mind, to a chart that I want to ask you some questions about.
MS. LEVY: So I want to put a sticker on -- another sticker -- I'll call it Exhibit Kessler-43, which I would like to also mark for -- just this page.
(Exhibit Kessler-43 marked for identification and attached to the transcript.)
BY MS. LEVY:
Q. This says -- 2003 Total Market, 12.12 Billion, is the title of the graph.
Are you with me?

Page 738

A. Yes. Actually, I think it's probably -- the graph is probably U.S. Pain Market, title. But this -- you can call the title anything you want.
Q. The single page we're referring to as "2003," I just want to understand the testimony that you gave a minute ago about this. This charts 1998 through what point in time? 2004?
A. 2004 is not a complete year. That's an expected year, I believe.
Q. Okay. And is this an illustration of the shift in prescribing that we were talking about?
A. It certainly is a shift in the increase. So you start with the red, which is long-acting opioids, I mean, as a -- as a group, right. So you have $783 million in '98 growing, in the red, to $3.5 billion.
And you also have some increase in short-acting opioids, going from about 970 to double.
So you have -- on the one hand, you have about a five-fold increase in long-acting

Page 739

opioids and a doubling in short-acting opioids.
Now, I just want to -- there are other graphs that I have over extended periods of time, but we picked out -- I mean, you asked me for a question, and I think this does correspond to some of the growth.
But, I mean, to be fair, we probably should have in front of us and pull up the growth over several decades. And I think you would see where -- where there was sort of a tipping point, where the growth started to accelerate. So it's that greater acceleration.
Q. What is the dip in 2004?
A. That's just not a full year. So if you --
Q. I see.
A. If you had a full year --
Q. It's a partial year?
A. It's a partial year. So that's why -- if you did a full year, I can assure you, it would be -- the growth is substantial.
Q. Has the shift in prescribing -- well, when you talk about -- when you said earlier in the deposition -- I wrote down these

Page 740

words -- "shift in prescribing" -- those were the three words I wrote down -- shift from what to what?
A. Well, I mean, you can -- you can do that, I mean, just in total number of scripts, right, for the opioid class. I mean -- or even the pain -- I think for the opioid class. Let's stay with that. And I think you can look at the increase in either total -- total prescriptions, total sales volume.
I think that was the -- that growth and that acceleration of that growth from basically -- you know, we can get the numbers from the 1980s, but I think this reflects the fact that if it's not a drug of choice, right --
I mean, there was -- there were a combination, and there may have been an IR product. Put a question mark around that.
But you would look at -- the sales volume was relatively small, and then there was a continued growth in increasing the number of prescriptions. That's what I mean by a "change in medical practice," how doctors actually

Page 741

prescribe.
Q. In your view, is all of the increased growth due to drug company misconduct or only part of the increased growth? Is it all of it that can be attributable to bad conduct or just a part of the increased growth?
A. Let me think about the answer to that question.
Q. I really just want a succinct answer. I don't want to know why you think that; I just want to know if all of the growth or part of the growth is due to misconduct.
A. I think the growth is due to the marketing and promotion. I would never -- I think it would be foolhardy to say all the growth in every instance. I wouldn't want to testify to that.
But this growth happened because of marketing and promotion. And that change in prescribing, it was due to the perception of opioids and the campaign to change prescribing.
Q. Did the -- did the growth at some point start to recede?
A. Yes.

Page 742

Q. When? Not a long commentary, just when?
A. I would need the graphs into the teen years, and it would depend by manufacturer and by generic. So it's a little complicated.
My sense is -- I mean, I'd want to have the graphs in front of me before -- certainly for certain manufacturers, it receded. There were changes that were made, and -- but I'd want the data in front of me before I'd give you an opinion on that question.
Q. So my question was, Did the growth at some point start to recede? Your answer was, Yes.
Then I asked you just to tell me when. Is your answer to that, I don't know?
MR. RAFFERTY: Object to the form.
A. I can't be precise here, in part, because --
Q. Is your answer, I don't know?
A. No, no. Well --
Q. I know you don't like to say that. I just want to know if you -- do you know, or

Page 743

don't you know? Answer that.
MR. RAFFERTY: That's not -- that's not the only two options.
Answer the question as best you can, or tell her you can't answer it.
A. So we have to be a little more precise in just -- we're talking about the growth of what? The pain market? The long-acting opioid market? The short-acting opioid market? The opioid market? I mean, all those are different questions.
OxyContin, Kadian, those are all -- would be -- have different answers, and we really would need -- I need the data in front of me to thoughtfully and accurately answer those questions.
Q. Let's talk about Kadian. When did the Kadian market recede?
A. You get more than everyone else, right?
Q. Let me see if you can answer my question.
A. Sure. Sorry.
Q. When did the market for Kadian

Page 744

recede? What year?
A. So let me just look at my --
Q. And the answer is either a year or you don't know the answer to the question.
MR. RAFFERTY: No.
Or you need to look at something in order to get the answer.
MS. LEVY: Right. I don't want --
MR. RAFFERTY: There is a lot of different answers.
MS. LEVY: I want a succinct answer to this question.
MR. RAFFERTY: But you don't get to dictate what that answer is.
MS. LEVY: Sure don't. But I do get to dictate that it's succinct.
MR. RAFFERTY: No, you don't. That's what the judge is for, the special master. You don't get to rule.
MS. LEVY: Indeed.
A. I don't have the graph -- I don't have the graph in front of me. I have data of what its market share was in 2011 and 2016. I have representations. And those are very

Page 745

small, and there was a -- there was a decrease from 2011 to 2016.
Q. So as you sit here right now with what you have in front of you, when did the market for Kadian recede?
I just want a -- I just want -- and if you don't know, you can say the words "I don't know."
MR. RAFFERTY: Object to the form.
A. I don't have the graph -- I don't have the graph --
Q. Okay.
A. Hold on a second. Is that true?
So if you look, for example, in Summit County, I think you see a receding around 2012 to 20- -- 2012, 2014.
If you look at Cuyahoga, you see, again, there's a receding between 2011 and 2012.
You see that in Cleveland, and you see that in Akron, and you see that in Ohio, generally. So I think -- I think -- I think it would be fair to say --
I don't -- the data I'm looking at

Page 746

as of right now is only between 2009 and 2017, so don't hold me to years before. I would want to see that data.
But I think it would be fair to say, if there were an inflection point in a rate of acceleration, it would be 2012.
Q. I'm sorry. I didn't understand that answer.
In 2012, did the market for Kadian increase or decrease?
A. It decreased. It you -- you asked for the rate of -- rate of deceleration.
Q. I didn't ask for any rates.
I just asked, did the market increase or decrease?
A. You said -- you said, when did it decline?
Q. Mm-hmm. A year. What year?
MR. RAFFERTY: Objection. He's answered the question.
A. So if you want to look at -- I can give you specifically -- we can -- we can put it up.
You know, in Ohio -- let's just

Page 747

take Ohio -- it was 20 -- 2009, it was 27,000. 2010, it was 25,000. In 2011, it was 26,000. It was relative- -- those numbers are relatively consistent.
In 2012, it was 5,792. 2013, 2,692. 2014, 1,063. 2015, 556. 2016, 450. 2017, 365.
I can give you those numbers nationally. I can give you Summit. I can give you Akron. So -- you have this document.
Q. Let's stick that on --
A. Sure.
Q. -- 44.
So for the record -- so the record is clear, the numbers that Dr. Kessler was reading is coming from the page that we're going to now mark as Exhibit 44.
(Exhibit Kessler-44 marked for identification and attached to the transcript.)
BY MS. LEVY:
Q. And when you were reading those numbers, I assume, Doctor, you're referring to numbers of prescriptions?

Page 748

A. So this is --
Q. Just is it the number of prescriptions or something different?
A. Let me -- let me just read the caption so I can be accurate. It is the total number of Kadian prescriptions that I just gave you.
Q. So is it your view that Kadian should be taken off the market? Yes or no?
MR. RAFFERTY: If you can answer it that way.
A. I've given no such opinion.
Q. I didn't ask you if you've given an opinion.
I'm asking you if it is your opinion, as you sit here today, that Kadian should be taken off the market, or, No, I don't think Kadian should be taken off the market.
MR. RAFFERTY: Or you can't answer the question as she has stated it yes or no.
A. I've not -- I've not given an opinion on that, ma'am, so I would have to think about that.

Page 749

I have no -- no opinion on that. My guess is, you know -- my guess is, after I thought about it, I would probably come out and say I'm not opposed to products being on the market if their marketing is well-controlled.

Q. Kadian came on the market during the Kessler administration; is that correct?

A. Came on in 1996.

Q. Kadian came on the market during the Kessler administration; is that correct?

A. Yes.

Q. Now, the FDA -- Kadian came on the market pursuant to the FDA's normal approval process for pharmaceuticals, right?

A. I wasn't involved in Kadian. I know it was approved in July of '96. I have no reason to believe there was -- there was anything that was -- that was different with regard to that approval process.

Q. Kadian's NDA application was accompanied by clinical studies, correct?

A. Let me -- I'd have to review --

Q. Do you know if Kadian's NDA included clinical studies? Do you know?

Page 750

A. Yes.

Q. Did it include clinical studies? Yes or no?

A. I have to go back and look. My memory is fading at the moment. If you'll give me a couple of minutes, I can tell you exactly. I'd have to refresh my memory of what those clinical studies were, because I'm just fading at the moment. But I'm happy to -- if you give me two minutes, I can double-check that.

Q. Did you read the clinical studies -- have you at any point in time read the clinical studies that accompanied the Kadian NDA?

A. I'm sure I -- I'm sure I looked at the basis for the approval at some point, but right now, I'm a little vague, and I'd have to review that.

Q. As you sit here right now, before looking at anything, you don't remember anything about those studies, do you?

MR. RAFFERTY: Object to the form.

A. I'm fading on those studies, to be honest. I don't -- I don't have a recollection

Page 751

of those studies. I'd have to refresh my memory.

Q. Okay. Do you have any reason to believe that the -- that CDER, under your administration, didn't do its job when it reviewed the Kadian NDA? Do you have any reason to believe it didn't do what it was supposed to do?

A. No.

Q. And you've said -- you've said before that you have a great deal of confidence in the FDA, right?

A. I said a lot of things about the FDA.

MR. RAFFERTY: Object to the form.

A. I'm not sure if I've used exactly those words. I mean, if you have a quote and wanted to give it to me --

Q. Well --

A. I've said a lot of things about the FDA.

Q. Let's not worry about what you've said in the past.

As you sit here today, tell me if

Page 752

those statements are true or false.

The FDA is the most important consumer protection agency in the world. True for false?

A. If you don't care what I've said in the past, why quote me? You're quoting me.

In the past, I have said that.

Q. Okay. I'm going to see if you can answer this question that I'm asking you. This is going to be really easy for you.

MR. RAFFERTY: Object to the commentary.

Q. This is true or false? The FDA is the most important consumer protection agency in the world. Is that true or false?

MR. RAFFERTY: Object to the time frame.

Q. I don't want to know what you've said in the past, what you think you've said in the past, what you might have said in the past.

I want to know, as you sit here today, do you agree that the FDA is the most important consumer protection agency in the world?

Page 753

MR. RAFFERTY: Object to the form.
A. I would agree with that.
Q. Okay. You always have and continue to have every reason to trust the judgment of officials of the FDA; is that correct?
MR. RAFFERTY: Object to the form.
A. I wouldn't -- sitting here today, I wouldn't say it like that.
Q. Okay.
A. I said I have enormous respect for the people who work at the agency, but like any other organization that has 10,000 people, there are people whose judgment I would trust with my life, and there are -- like any organization, there are clunkers.
And so I would not make a blanket statement across the board. I have enormous respect.
Q. Janet Woodcock, the head of CDER, you would put her in the category of someone you have enormous respect for?
A. I appointed Janet.
Q. That's not the question I asked.
Do you have enormous respect for

Page 754

Janet Woodcock?
A. Respect? Sure. I appointed her. I picked her out. She was a, you know, three-level medical reviewer, and I made her the head of the center ten years ahead of when she was supposed to be. I have enormous respect.
Do I agree -- I have enormous respect for her contribution to service, to her integrity. Has she made mistakes? Absolutely. Do I disagree with her? Absolutely. Have we had conversations like that? Absolutely.
I defended Janet Woodcock, I mean, you know, pretty vigorously because I thought people at the agency should get defended in certain circumstances.
Q. What about Carl Peck? Would you say the same about him?
A. Carl Peck, you have to love. Carl Peck -- I would trust Carl Peck with pharmacokinetics because he sees pharmacokinetics in everything. And I think he contributed and we worked mightily together.
Do I agree with him on everything?

Page 755

Absolutely not. Do I think every question can be answered by a PK analysis? Absolutely not. Did he make a mistake on pilot drug, et cetera? We could spend hours talking. But I love Carl Peck, and enormous respect for Janet.
Q. The FDA has the highest safety and efficacy studies in the world, right?
A. Studies in the world, no. FDA doesn't do studies. The manufacturers does the studies. So I'm not sure what that -- the question means.
Q. The doctors and scientists at FDA are as smart and talented as any you've ever seen; is that right, sir?
MR. RAFFERTY: Object to the form.
A. That's exactly the kind of statement that I made earlier. If you're asking me, there are those who are very talented, and there are those who are clunkers, and there are those who could earn umpteen dollars times their salary on the outside and are pure gold, and there are others who make mistakes. And even those who you trust sometimes make mistakes. And we all do that.

Page 756

Q. Do you agree that the United States food and drug laws have the highest safety and efficacy standards in the world?
MR. RAFFERTY: Object to the form.
A. I did at a point in time.
Q. Do you agree now, as you sit here today?
A. I think in certain areas, we may be being usurped by certain of the European -- in certain areas. I think that was probably true at a point in time, but I have some concerns in certain areas.
Q. If a company gets a warning letter and the company wanted to be a model citizen, one thing it would do -- the first thing it would do is immediately stop using the offending promotional materials. That's one thing you would want to see a company that got a warning letter do, correct?
A. Sure. But I think there would be something you'd want to do first.
Q. Another thing you would want a company to do when it gets a warning letter from the FDA about promotional materials is to

Page 757

work with the FDA to formulate a corrective action plan, right?
A. Sure. But I would think there would be something even more important.
Q. What first? What would one want to do first?
A. You'd want to look and see not just what this promotional material was or what your corrective action plan, you would want to understand the corporate strategy or the corporate culture that contributed to that warning letter, and you would want to make sure you would change that corporate culture or that corporate strategy rather than just discarding X piece of paper or coming up with a plan. That's what I think it is more important when you got a warning letter.
Q. So if you're advising a company as to how to be a model citizen and do the right thing when you get a warning letter, you need to figure out why the statement got in and correct that as a matter of corporate conduct? Is that what you're saying?
A. Sure. But you'd have to ask

Page 758

yourself -- there's a term -- and I'm not a big fan of it, the term. It's a little bit of a slogan, but it's a culture of compliance. And is there anything in that culture of compliance that is off, that begat that warning letter.
Q. You'd also want to work with the FDA and create a corrective action plan that was effective, correct? Yes or no?
A. Sure, yes.
Q. And you are aware that Actavis got a warning letter with respect to Kadian. That's something that you talk about in your report, right?
A. 2010, I believe, yes.
Q. And, in fact, Actavis did immediately stop using the materials. You're aware of that?
A. I am.
Q. And Actavis also worked with the FDA to create a corrective action plan, correct?
A. Correct.
Q. And you are aware that the FDA agreed with and said it appreciated the

Page 759

corrective action plan, correct? Are you aware of that?
A. I'm not sure the word "appreciated," but I'll take your stipulation to that. I don't recall, but I'll -- I'm sure the FDA said something akin to that.
Q. And part of the corrective action plan was to send Dear Healthcare Professional letters to every physician who had received the projects materials.
Are you aware of that?
A. Correct.
Q. In addition, part of the corrective action plan was to send additional letters out to consumers, correct?
A. Correct.
Q. Okay. And you don't have any reason to believe that the FDA was dissatisfied with that corrective action plan, do you?
A. Correct.
Q. Okay. There was no enforcement action or any further action taken on Kadian by the FDA at any point in time after that, correct?

Page 760

A. Correct. And we see the decrease in numbers and eventually the decrease in promotion, et cetera, that followed shortly, and we see this inflection point in Kadian's sales.
Q. Do you believe that Actavis did the right thing when it got its warning letter?
A. I have no reason to doubt that.
Q. Okay. There's another document that you cited in your report in paragraph 520 that you take issue with for Actavis.
A. If I can find my report.
Q. Your report is buried in my pile, too. Let's look together.
A. 520?
Q. I think that's correct. Let me turn to it.
MS. LEVY: There's a request for a break. Let's go off the record.
THE WITNESS: I think 520 raises some questions.
MS. LEVY: Hang on a second. Let's go off the record.
VIDEO OPERATOR: 4:40 p.m., we're

Page 761

off the video record.
(Recess from 4:40 p.m. until 4:53 p.m.)
VIDEO OPERATOR: 4:53, we're on the video record.
BY MS. LEVY:
Q. Doctor, you once referred to the FDA processes as being the gold standard for drug approval.
Do you still have that opinion today?
A. I think so.
Q. How many opioids were approved in the Kessler administration?
A. I don't know -- I mean, the ones obvious -- there were approved -- let me just do it in my head. Duragesic was approved before me.
There were two. There was Kadian, and as far as brand name drugs, Kadian and Duragesic -- I'm sorry -- Kadian and Oxy were done during that seven-year period. I'd have to look and see how many on the generic side.
Q. Do you know the number of

Page 762

opioids -- just do you know the number of opioids that were approved during the Kessler administration?
A. I can tell you NDAs.
Q. How many? Number only.
A. I believe there were two NDAs.
Q. How many ANDAs?
A. I don't have that number.
Q. You don't know?
A. I don't know.
Q. The FDA continues to approve opioid products on an ongoing basis, correct? Let me -- I worded that poorly.
The FDA continues to approve new opioid products on an ongoing basis, continuing through today, right?
MR. RAFFERTY: Object to the form.
A. There's an issue with regard to that in my conversations with the Commissioner, but the way the statute is written, there's some discussion of whether that needs to be changed.
Q. Not my question.
The FDA continues to approve

Page 763

opioids, this year has even approved opioids, correct?
A. This year, it would be fair. But when you say "continued," you're implying into the future, and I'm just saying there is an issue about that.
Q. Okay. The FDA approved new opioids in 2015, '16, '17, '18 and '19, correct?
A. And some to great criticism.
Q. No doubt that the FDA has been criticized widely by some folks for doing so.
But it continues to approve these products, correct?
A. Including me.
MR. RAFFERTY: Object to the form.
Q. And there have been a number of citizens' petitions and other requests to the FDA to make changes and to make -- to take certain actions with respect to opioids on the market.
You're aware of those, right?
MR. RAFFERTY: Objection.
A. We've discussed those in the past two days.

Page 764

Q. And you disagree with the FDA's opinions and outcomes in responding to those petitions? You disagree with the FDA in that, right?
MR. RAFFERTY: Object to the form.
A. I don't think that's a fair statement. That's not my testimony. If you want to show me a specific sentence in FDA, I can tell you what I would agree with and what I disagree. I won't make a blanket statement --
Q. That's fair.
A. -- that I agree or I disagree.
Q. And I believe we established this earlier in the record, but just in case.
You are not giving testimony or speaking for the FDA, correct?
A. That's correct.
Q. You haven't been employed by the food -- by the Health and Human Services Department since the -- 21 years; is that right?
A. You can do the math at this hour. But I would certainly -- it's very important, underscore it, put an asterisk, put an

Page 765

exclamation point. I'm in no official capacity. Sometimes I get put on television because they're not -- sometimes I get put on television because the agency is not speaking. But I have no official capacity.

Q. Okay. There are plenty of things that you disagree with the FDA on, right?

A. Things I agree with them and things I disagree with them.

Q. Okay. Now, the -- one of the things you believe is that Kadian should not be prescribed for chronic pain, right? Or is that an overstatement?

A. So I think if you did that, if you just left it that way, I think that would be inaccurate.

Q. Okay. Do you have any -- strike that.

Kadian was approved by the FDA in 1996 for use in patients with chronic moderate to severe pain who require repeated dosing with a potent opioid analgesic, correct?

A. I thought it said continuous, around-the-clock. Do you want to just give

Page 766

me -- maybe I'm misreading.

Q. Let me -- let me read you --

A. Just give me the indication. I can pull it. Let me pull it.

Q. I just want to ask -- I'm asking -- we're going to do that in a minute, but listen to this specific question, and I would like to know if you agree or disagree.

A. Okay. I'm just pulling the label so I can be exact. But go ahead. I'm listening, ma'am. I don't want to delay.

Q. No. Take your time. Do what you need to do. Put the label in front of you.

And for the record, are you looking at your report?

A. Just looking at the schedules that have the labels, and I'm looking specifically for Kadian and multiple changes, and let's just look at the indications section -- I'm just trying to get the indications section -- interactions with alcohol -- go ahead. Just read me the indications section, or read me whatever you want.

Q. So no, that's not my question,

Page 767

actually. I want to wait until you can pay attention to the question I'm going to ask you.

A. Sure. And I apologize. I'm just trying to pull the labeling.

Q. Would you like to see the Kadian current label?

A. I'd love to see it in 1996. That's what I -- and I apologize --

Q. I'm going to give you just another minute, and then I'm going to move on with my question.

A. Keep going on, please.

Q. Okay. I'm going to say a statement, and I want to know if you agree. And here is the statement: Kadian was approved by the FDA in 1996 for use in patients with chronic moderate to severe pain who require repeated dosing with a potent opioid analgesic.

That's true, right?

A. No, I'd want to see the label before I'd answer that question.

(Exhibit Kessler-45 marked for identification and attached to the transcript.)

Page 768

BY MS. LEVY:

Q. Let's mark -- let me hand you what I've marked as Kessler Exhibit 45.

A. Thank you very much, ma'am.

Q. Okay. And this is a document dated July 11th, 1997. You see in the top right-hand corner?

THE WITNESS: Can I ask someone just get me the Kadian label, the approved label, please? Yeah, thank you.

A. I see this.

Q. Okay. And you recognize the letterhead on this document as FDA Center For Drug Evaluation and Research. You recognize that letterhead?

A. I know that letterhead.

Q. And the Center For Drug Evaluation and Research is often referred to as CDER, right?

A. Correct.

Q. CDER's understanding on July 11th, 1997 was that Kadian was approved by the FDA in 1996 for use in patients with chronic, moderate

Page 769

to severe pain that require repeated dosing with a potent opioid analgesic.
Do you agree with that?
A. You've got to show me the label and I can answer that question.
Q. Okay. In --
A. This is a medical officer's review. We don't know whether that's shorthand. We don't know at what point in time.
Just somebody show me the label. This shouldn't be a hard question to answer. The answer to your question is exactly what it says in the approved label.
And I'm sorry, I just can't pull it up at this moment in time.
Q. Is it okay to prescribe Kadian to patients with chronic pain?
MR. RAFFERTY: Object to the form.
A. Can I see the label and I'll be -- I'm not going to answer --
Q. You can't answer that without seeing the label?
A. I want to see the label, yes. I want to see the label.

Page 770

Q. Without seeing the label, can you answer this question: Is it okay to prescribe Kadian to patients with chronic pain?
A. Again, either show me the label or I can't answer the question. I don't want to guess. My understanding is that there was around-the-clock, extended, continuous, and those things are in the label.
But I don't have -- my memory is fading and I'm just -- the courtesy of please show me the label and I can answer that question, or I can't answer the question.
Q. Let me point you back to Exhibit 45. You'll certainly agree with me that CDER believed that Kadian was approved for patients with chronic pain. That was CDER's statement, right?
MR. RAFFERTY: Object to the form.
Q. Yes or no? Did you hear my question, Dr. Kessler?
A. I heard your question.
Q. Okay. What was my question?
A. Your question -- let me point you to Exhibit 45; you'll certainly agree with me

Page 771

that CDER believed that Kadian was approved for patients with chronic pain. That was CDER's statement.
The label I have is Kadian capsules approved for use in the introduction is an extended-release oral formulation of morphine indicated for the management to moderate or severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.
That's what I remember. So if we can -- and that's from an FDA document. But let's -- if someone gets me the label, I can -- we can be exact. I mean, I would think --
Q. Keep going.
A. I would think after I spoke on Duragesic, I mean, and an extended release morphine several years later, that some of that would be --
Q. You see what I've highlighted in Exhibit 45?
A. Yes.
Q. Is CDER correct or incorrect, or you don't know? Which is it?

Page 772

A. If this does not correspond to the label, this is incorrect.
Q. And you don't know whether it does or doesn't?
MR. RAFFERTY: Object to the form.
Let the record reflect counsel refuses to show him the label.
A. Okay. I have to be precise here. If you can show me the label and what it's approved for in 1996, I can be exact. That's my only request.
(Exhibit Kessler-46 marked for identification and attached to the transcript.)
BY MS. LEVY:
Q. So I'm going to show you what's marked as Exhibit 46.
A. Thank you so much.
Q. And I'm going to give you -- I'm going to ask you to take a look at that document and tell me -- the question is this. Do you --
A. Can we just establish the date of this, kindly?

Page 773

Q. Look on the front page, bottom left. It's the current Kadian label.
A. Correct.
Q. My question to you is: Do you have any problems with this label?
MR. RAFFERTY: Object to the form, overly broad.
Q. Yes or no? That's all I want to know.
A. Yes.
Q. Okay. This label is no good, in your view?
MR. RAFFERTY: Object to the form.
A. I didn't say that. I just said -- you asked me if I have problems with that. The problem is, this talks about a drug being indicated for long-term opioid treatment and extended release treatment.
Again, there's good parts of this label, around the clock, and for which alternative treatment options are inadequate.
The problem is, is it didn't disclose that there's not adequate and well-controlled trials that support that

Page 774

indication.
So this is -- in that case, you would want to -- I mean, if I were Commissioner at the time, I would say, we can make that statement, right. I mean, I would probably want to emphasize cancer as I did in '94, maybe in a rare small incidence beyond that, but I would want to put in this that there was not adequate and well-controlled clinical trials to support this, but we're doing it anyway.
Q. Okay. So the Kessler that's here for litigation believes that the label is not supported by adequate and well-controlled trials. Is that a fair statement?
MR. RAFFERTY: Objection to the characterization.
Q. Yes or no?
A. So Dr. Gottlieb, Dr. Califf, Dr. Woodcock all believe -- all have stated, right, that there is not adequate and well-controlled clinical trials to support long-term use for opioids. That is not a litigation position. If you look --
Q. That's your opinion in this

Page 775

litigation, right?
A. Well --
Q. That is your opinion today in this litigation?
MR. RAFFERTY: Objection.
Don't interrupt him. If you're going to characterize something as "litigation Kessler," then he has a right to respond to it.
Q. And is it your opinion --
A. Can I --
Q. -- that this label --
A. I need to finish my answer.
Q. -- just yes or no, is your label --
A. I need to finish my answer.
Q. Okay. Go ahead.
MR. RAFFERTY: You don't have to answer anything yes or no just because she tells you to.
A. I'm trying to -- I would like to --
Q. I'd like for you to give me a succinct answer. Is that label flawed?
A. Yes, that label is -- but please, this is so important, okay. The randomized

Page 776

adequately controlled trial that we have, the space trial, there's only one, shows no efficacy benefit from long-term opioids. That's the one we have. There are others that are in the works.
Making an indication without adequate and well-controlled clinical trials by definition is flawed.
Sometimes you do flawed things when you're in a corner, right. Things -- there's been a practice in place for 20 years. You just don't want to hurt anyone. You want to leave the door open beyond cancer pain, right. Because when you're at FDA, right, you realize that somebody may, because of your action, jump out of a window if you deprive them -- and you lose sleep on that, right, so you're very careful on what you do.
But that is a flawed statement because it is contrary to the adequate and well-controlled scientific evidence. That is not a litigation position. That is the fact.
Q. Okay. So can you fix it for me, please. Take that pen that I just put in front

Page 777

of you and fix that label.
MR. RAFFERTY: Objection. He doesn't have to do that.
Q. Yeah. Can you do that?
MR. RAFFERTY: No, he doesn't. He doesn't have to draw anything.
A. I can give you certain recommendations. I mean, I have no opinion on that. But I would give you certain elements --
Q. Now, you either can or can't. That's what I want to know. Are you able to take --
A. I can give you --
Q. Just a minute. It's a yes or no question. Can you do this: Can you take that pen and just fix the Kadian label? Is that a thing you could do?
A. I could do that if you want to spend the next maybe hour and my thinking about it, and I can give you the elements -- I probably couldn't give it to you as artfully done, but let me give you the elements that I think have to be in this label.
Q. I just wanted to know if it's

Page 778

something that can be done. So you disagree that this is an appropriate label. You disagree that this label is not appropriate?
A. I don't think --
Q. It is not appropriate --
MR. RAFFERTY: Objection to the -- quit cutting the witness off.
MS. LEVY: Stop talking over me.
MR. RAFFERTY: No, I'm not --
MS. LEVY: You have plenty of time to object.
MR. RAFFERTY: No.
Q. In your view, Dr. Kessler, this label is flawed. That's your testimony?
MR. RAFFERTY: Object --
Q. Simple as that, right?
MR. RAFFERTY: Object to the form.
A. I think what I testified to a couple of minutes ago is, there were some good aspects of this label, right, but there was still need for improvement in this label that reflects the current -- the science of this and could more appropriately further protect the public health.

Page 779

Q. You don't think -- do you think opioids are appropriate to use for long-term pain? Do you think that, as you sit here today?
MR. RAFFERTY: Object to the form.
Q. Are they appropriate? I'm not asking about anything else other than your opinion as to whether they're appropriate.
MR. RAFFERTY: Object to the form.
Q. Yes or no?
MR. RAFFERTY: Object to the form.
And you don't have to answer yes or no.
A. I think a physician in his or her judgment, recognizing that there is not adequate and well-controlled trials to support that decision for safety and effectiveness, after -- in either cancer pain -- in certain types of cancer pain or in some rare instances of non-cancer pain, maybe as third line, maybe as fourth line, but I would use them sparingly in light of the fact that there is not adequate and well-controlled clinical trials.
But if your back's against the

Page 780

wall, you know, we all do what we have to do.
Q. Have you ever taken opioids?
MR. RAFFERTY: Objection.
Do not answer that question.
That is wholly inappropriate, and you know it.
Q. You've prescribed opioids certainly, right? I think you told us that yesterday.
MR. RAFFERTY: Mark that part of the transcript for me, please.
Q. Have you?
A. Yes. I --
MR. RAFFERTY: That is an abusive question.
A. I have either prescribed morphine in the oncology wards. I may have prescribed certain combination products, not for its pain effect, but for its antitussive effect, for its central nervous effect in certain neurological antitussive episodes.
But I think -- I mean, I do it, you know, I probably -- you can count on a hand or two hands the number of times I've written in

Page 781

my career -- I've been a hospitalist, so maybe, you know, the service may have prescribed when I'm the attending, but I -- it's very occasional.
Q. And I think we established this earlier in your testimony. You were a pediatrician; is that right?
A. Still am a pediatrician.
Q. And you are not an oncologist, are you?
A. I did a lot of oncology. I spent an enormous amount of time because I was the attending --
Q. Are you an oncologist?
A. No, I'm not, but I do a lot of -- when you're the hospitalist on the adolescent floor, the floor is filled with --
Q. Sure. That wasn't my question.
A. But I did --
Q. Are you an oncologist?
A. No, but I've done a lot of pediatric oncology.
Q. Sure. And you told us yesterday on the area of your expertise that you took a

Page 782

marketing class. You don't have a degree in marketing, do you? Do you have a degree? It's a very easy question.
A. It's not an easy question.
Q. Okay. Do you have a degree, yes or no?
A. Well --
Q. Or you can't answer it?
A. No, I can answer it. I mean, so I did --
Q. Stop. If you can't answer it with a yes or no --
A. I did -- I did --
Q. Can you answer it with a yes or no?
A. I have something called an advanced professional certificate from the NYU Stern School of Management. They keep on asking me for donations. They think I'm a graduate, but I only did deliberately the first year, the basic courses in business school -- and that included market --
Q. You don't have a degree.
A. I have an advanced --
Q. That's not a degree.

Page 783

A. I'll let others characterize the degree. Believe me, I'm trying to give away degrees at this point. I have enough degrees.
Q. And do you have consider yourself to be an expert in marketing?
A. I think I have -- when it comes to --
Q. Yes or no?
MR. RAFFERTY: No, it's not a yes or no question. It's not.
Q. Let's back up. Can you answer this question with a yes or no?
A. With regard to drug marketing --
Q. You do think you're an expert?
MR. RAFFERTY: Quit cutting off the witness.
Q. Yes or no?
A. Yes.
Q. Okay. That's all I wanted to know. And I don't even want to know why.
All right. Let's take a look at a document that I'm marking as Exhibit 47.
(Exhibit Kessler-47 marked for identification and attached to the

Page 784

transcript.)
BY MS. LEVY:
Q. Exhibit 47 --
A. Yeah.
Q. -- this is a document that you have cited in paragraph 389.2 in your report, correct?
A. There's three documents that I've cited. I think there's a -- if you can hand me the February document there's --
MR. WEINBERGER: Can I interrupt for just a second?
Counsel, let me refer you to the rules of the Northern District of Ohio Federal Court, 30.1, Decorum: Opposing counsel and the deponent must be treated with civility and respect. Ordinarily the deponent must be permitted to complete an answer without interruption --
MS. LEVY: Pete, you can cut this out. You are now filibustering and wasting time on purpose.
MR. WEINBERGER: Let me finish.

Page 785

-- by counsel --
MS. LEVY: I'm not going to allow you to waste my -- we're going to add time --
MR. WEINBERGER: You can add time.
MS. LEVY: -- on this record --
MR. WEINBERGER: You can add time.
MS. LEVY: -- for as much time as you take reading rules to me.
MR. WEINBERGER: Stop talking over me. 30 seconds. I am asking you, as an Officer of the Court, to follow the rules and to act with civility towards this witness.
Absent that, we will take this up with the Court.
(Exhibit Kesslery-48 marked for identification and attached to the transcript.)
BY MS. LEVY:
Q. I'm going to hand you what has been marked as 47, and you also have --
A. Let's go to the paragraph number.
Q. 47 and 48 you have in front of you.

Page 786

MR. RAFFERTY: I think she's talking about exhibits, not the report.
THE WITNESS: Yeah.
A. But these are cited in 520, is that what it is?
Q. 389.
A. 389, paragraph 520.
Q. Yeah. I have very limited questions.
A. Sure.
Q. So I want to be clear and transparent with you, Doctor.
A. Sure.
Q. I do not believe that I'm getting succinct questions, so I reserve every right to go to the special master and ask for extra time with you.
I'm going to ask you really careful questions and see if you can answer just what I ask and nothing more. Can we try our best to do that going forward?
A. I would love to get out of here --
Q. Okay. So --
A. -- as much as you would.

Page 787

(Reporter interruption.)
Q. Okay. Let's talk about the document that I just put in front of you that's Exhibit 47.
A. Yes, ma'am.
Q. Okay. You cite that this document -- in your report, do you cite that -- this document in your report, sir?
A. I do.
Q. Okay. You can see and will agree with me that this is a draft document? Do you -- can you see that?
A. I see there's handwriting on this -- I see there's handwriting on this document. I don't see the word "draft," but feel free to point it to me.
Q. Okay. Let's ask a different question. Do you know if this is a draft or a final document?
A. I don't know the answer to that -- I don't see the word "draft" on it. I do see a handwriting. And last night I noticed something in this, so I may be able to anticipate your question.

Page 788

Q. Do you know if this document that we are looking at together was ever used? Do you know the answer to that?
A. I don't know.
Q. Okay.
A. I don't know the answer to this.
And to make life a little easier, I did see last night, in pulling this, that there's some handwriting changes with peaks and valleys -- I mean, this does not look -- this looks like a final presentation in February. This has this crossed out. And my report should reflect that.
Q. Okay. Let's pick up what's marked as Exhibit 8 -- 48, I'm sorry. Do you know if Exhibit 48 is a draft document or final document? Do you know?
MS. AMINOLROAYA: Can you identify the document, Counsel?
MS. LEVY: I'm sorry. I just handed it to counsel.
Q. Do you know the answer to that question?
A. I can only tell you that it is not

Page 789

marked "draft," and companies tend not to do presentations that -- where it's not -- I mean, my experience is, you mark things "draft."

Q. So you assume that it's a final?

A. No. My testimony is, it's not marked "draft." I see "draft" nowhere on this document. I see a different version in March 23rd.

I have questions about the March 23rd document because I do see handwritings. I don't see that same handwritings here.

Q. Do you know if Exhibit 48 is a draft or final? Do you know that?

A. I know it doesn't say "draft."

Q. I'm going to point your attention just to the Bates number on the bottom left-hand corner.

A. We're in 48?

Q. In 48.

A. Yeah.

Q. That's labeled 1554. Do you see that?

A. Yes.

Q. What does it say under --

Page 790

A. 1554.

Q. What does it say there?

A. It says, insert picture of dosing guide.

Q. Does that indicate to you, Doctor, that this is a draft document and not a final?

A. No. It depends how it's constructed. I wouldn't want to give any opinion on that.

Q. Okay. So you don't know?

A. I would not give any opinion on that based on that paragraph.

Q. Okay. And now let's look further at 1527 in the same document of Exhibit 48, 1527. This is two pages in.

A. Yes.

Q. What does that slide say?

A. Pain slides, insert summary slides from Marion's deck.

Q. Now that you've looked at that, doesn't it look to you, sir, like this is a draft document, not a final document?

A. I think it's possible. I mean, I think that raises some questions.

Page 791

Q. Okay. Now, there's a difference in marketing that results in new prescriptions and marketing that results in substitution of a product. Do you agree with that?

A. Yes, and you can see that kind of analysis in certain companies' documents, yes.

Q. Okay. Not all marketing has the impact of having new patients get opioids. You would agree with that, right?

A. Correct.

Q. It's a simple question.

A. I said --

THE WITNESS: Gerard, can I just see General 1, please.

Q. Do you agree with the statement that not all opioid marketing would result in new patients getting opioids? Do you agree with that? Simple question.

A. I think it would be fair to say there is a time where companies are trying to get market share away from something, and a -- can I get -- I'm sorry -- influence on doctors.

I think there's both. There's new market share -- I mean, there's substitution,

Page 792

and I think those things are tracked.

I didn't see it from Actavis. But I think those things are tracked in a number of documents with a good deal of specificity that I have seen.

So for example, you can have in OxyContin continuing Rx's and new to brand and new starts and switches.

So here you have what's called new starts, which would be 36.7, and switches, which would be substitution, so both can go on.

Q. Without looking at the transcript, what was my question to you?

MR. RAFFERTY: Objection.

You don't have to answer that.

Q. Do you remember what I asked you?

MR. RAFFERTY: You do not have to answer that.

If you've got a question for the witness, ask the question.

Q. Do you remember the question I just asked?

A. Please, let's go on.

MR. RAFFERTY: It's not a memory

Page 793

test. Read the question back to --
Q. So you told us yesterday another -- you gave us -- well, strike that.
One of the things -- one of the things we asked you about yesterday, Doctor, was your payment for your work in this case.
I wrote down in my notes that you told us yesterday that you had made millions of dollars in testifying in lawsuits. Do you recall that testimony?
A. Two points I'm not sure I'm tracking. You're asking me for my payment for work in this case, and that I've made millions of dollars. Those things were unrelated questions.
Q. Okay. So I was unclear -- I was unclear yesterday, so let me ask you some questions to clear that up.
How much have you been paid for your work in this case?
How much have you --
(Reporter interruption.)
A. I'm sorry, I apologize --
Q. How much have you charged for your

Page 794

work?
A. (Nonverbal response.)
(Reporter interruption.)
MR. RAFFERTY: You have to say "zero."
THE WITNESS: Zero.
Q. How much --
A. Let me just make sure I'm reading -- listening to your questions -- your exact questions.
How much have you been paid?
I've been paid zero in this case.
Q. How much have you billed for your time and your work in this case?
A. "This case" being the MDL?
Q. Yes.
A. Zero.
Q. Are you working for free in the MDL?
A. No.
Q. It's just you haven't submitted your invoices yet?
A. Fair.
Q. So you estimated yesterday that you

Page 795

had spent hundreds and hundreds of hours. Is that correct?
A. Fair.
Q. Okay. But you can't say more specifically than that?
A. I have not added it up.
Q. You have kept track of it somewhere though; is that correct?
A. There are numbers on -- you know, they're on scribbled papers, yes.
Q. So you could look that up and get that information to us?
A. I'm sure at a certain point, you know, those -- I'm sure when invoices get done, whatever agreement you have, whatever the rules are, I leave it to counsel to work out these things.
Q. And now, going to your income for testimony in litigation in total -- not just in this case, all litigation -- I think that was what you said you had made millions of dollars doing that. Is that correct?
A. Over a ten-year period, correct.
Q. And can you be more specific than

Page 796

that? Do you know how many millions of dollars?
A. No.
Q. You haven't kept track of that?
A. No. You have to ask -- I don't do the finances.
I know it's certainly millions. I think that would be accurate. I don't know exactly. Over a ten-year period.
Q. And is it over $10 million?
A. I wouldn't want to hazard a guess.
Q. You genuinely don't know?
A. I genuinely don't know. I've not added it up, what the total is.
Q. Your current billing rate is a thousand dollars an hour; is that correct?
A. Yep.
MS. LEVY: All right. I'd like to take a short break to figure out how to use my last minutes. If we want to, we can just stay right here.
VIDEO OPERATOR: 5:29, we are off the video record.
(Recess from 5:29 p.m. until

Page 797

5:54 p.m.)
VIDEO OPERATOR: 5:54, we are on the video record.
BY MS. LEVY:
Q. Thank you, Dr. Kessler. We have just a few number of minutes and a lot of defendants, so I appreciate your patience while we try to figure out how to allocate our last little bit of time.
The first thing I want to clear up for the record is administrative with respect to Exhibit 42.
Can you tell us for the record -- so we don't have to copy the whole book -- what pages of Exhibit 42 that you referred to earlier in this deposition?
A. I believe they are tabbed, ma'am, and the pages include 219 and 220.
Q. Okay. You understand that Actavis did not acquire Kadian until December of 2008? You know that, right?
A. Correct.
Q. So any documents with respect to Kadian prior to 2008 are not Actavis documents.

Page 798

You understand that, right?
A. Are not Actavis documents? I believe Alpharma owned it until 2008. So that would be correct. That would be correct.
Q. You anticipated my next question.
And is it your position, sir, that Alpharma is responsible for inappropriate marketing with respect to Kadian?
MR. RAFFERTY: Object to the form.
A. I didn't sort out -- don't take the manufacturer too seriously. I don't mean that. I don't mean to diminish -- look at the drug and the date. The documents may be -- Kadian -- even sometimes something is labeled Allergan. It can be used sometimes -- sometimes certain manufacturers appropriate certain sales promotional materials when they acquire -- it's complicated.
So just look at the drug and the documents and whoever the manufacturer is -- is at the time of the document that I have referenced is what I mean in the report. I'm drawing no legal conclusion about if I buy a company, do I buy what I'm responsible for. I

Page 799

leave that to other -- to the lawyers and others to sort out. I'm not sorting out relative responsibilities when a company acquires another -- when a company acquires a drug.
Q. You're planning to offer an opinion that the marketing of Kadian had some impact on the opioid crisis, right?
A. Yes. I mean, and use the evidence there regardless of the manufacturer.
And again, I'm just referring to this as a general rule in the report because there is a number, for example, of Cephalon we saw being acquired by Teva. So they may be Cephalon; they may be Teva; they may be Teva/Cephalon. Just focus on the drug.
Q. You made no effort to sort out what part of the marketing problems were attributable to Actavis versus Alpharma, did you?
MR. RAFFERTY: Object to the form.
A. Correct.
Q. Okay. Thank you.
And so on a relative basis, you

Page 800

don't believe that the problems you saw with the marketing of Kadian on a relative basis were that big of a problem, honestly, do you?
MR. RAFFERTY: Object to the form.
A. I think when -- I think there are other promotional campaigns that had a much greater impact than Kadian's.
Q. One of the things that I was left scratching my head on -- well, place-hold that.
You understand that the FDA tracks prescription data, right?
A. FDA buys data that tracks prescription data.
Q. You're exactly right.
You understand that FDA purchases data in order to be able to track prescriptions, right?
A. Correct.
Q. And it does, in fact, use the data that it purchases for that purpose? You know that?
MR. RAFFERTY: Object to the form.
A. It can for different purposes.
Q. And the FDA, from the Kessler

Page 801

administration all the way to today, has taken some actions and made changes with respect to its views on opioids? Is that a fair statement in general?
A. Correct.
Q. Is there any action taken by the FDA, any specific action, that you believe it took that it couldn't have taken earlier?
MR. RAFFERTY: Object to the form.
A. I don't understand the question. Sorry.
Q. The institution of the REMS protocols, FDA could have done that earlier, right?
A. It did risk maps earlier. The 2007 statute gave it specific authority -- the FDA 2007 gave the FDA authority, for example, to order safety studies. Only recent legislation, the Cures Act, gave FDA authority to require efficacy data to compel it once a drug is on the market.
Q. Couldn't have done it any earlier, in your view? Could not have?
MR. RAFFERTY: Object to the form.

Page 802

A. It's a legal question --
Q. You don't know?
MR. RAFFERTY: Object to the form and the interruption of the witness again.
Q. Do you know?
MR. RAFFERTY: Which question do you want him to ask [sic]?
Q. I want to ask if he knows if the FDA -- just a yes or no, if you know. I don't want to know what it is. I just want to know, does Dr. David Kessler --
A. I can answer your question.
Q. -- know the answer to this question?
A. Yes.
MR. RAFFERTY: And if he can give the answer.
Q. Could the FDA -- does Dr. David Kessler know this? Could the FDA have acted earlier? Does he know the answer?
MR. RAFFERTY: Object to the form.
A. I'm requiring on the long-term efficacy study, not a safety study. I can tell

Page 803

you that FDA's position, in talking to Dr. Gottlieb and in the Cures Act was that FDA required congressional statutory authority.
Q. So it could not have acted earlier?
A. That was FDA's position of late in talking to the Commissioner of what he stated.
Q. Could the FDA have requested label changes or changes in indications to various opioids a long time ago, if it wanted to?
MR. RAFFERTY: Object to the form.
Q. Could have done that, right?
A. Certainly it could have. It can always request, correct.
Q. And another thing that left me scratching my head is -- because I'm going to wonder this -- is it true that you do not know how much money you made last year?
MR. RAFFERTY: Object to the form, asked and answered.
A. I do not know how much money I made. I can tell you my wife does the finances.
Q. Do you have to sign your tax return?

Page 804

A. For last year?
Q. 2018.
A. Yes, I filed. I signed the form that asked for an extension. I've seen no tax returns.
Q. What about 2017?
MR. RAFFERTY: I'm going to object. And quite frankly --
MS. LEVY: You're welcome to object.
MR. RAFFERTY: -- this is getting harassing, and if it continues, we're going to just instruct him not to answer.
MS. LEVY: You're welcome to do that.
MR. RAFFERTY: He's not going to talk about how much money he makes --
Q. Dr. Kessler --
MR. RAFFERTY: -- overall because that's not relevant under Rule 26, as counsel well knows.
Q. What are your sources of income aside from the income that you're getting from

Page 805

testifying?
MR. RAFFERTY: Objection.
Q. What other sources of income do you have?
MR. RAFFERTY: You don't have to answer that question, Doctor.
A. I'm happy to answer that question, unless counsel instructs me otherwise.
Q. What are they?
A. I'm happy to.
I have a number of different sources of income. I have book royalties and book contracts. I told you about private equity. I have academic salary. I have consulting.
Q. And you truly don't have any idea how much money you make annually?
MR. RAFFERTY: It's done. The last question was asked.
Q. You have no idea?
MR. RAFFERTY: You don't have to answer any more questions, Doctor.
MS. LEVY: Are you instructing the witness not to answer that question?

Page 806

MR. RAFFERTY: I am, because it's been harassing.
MS. LEVY: Okay.
VIDEO OPERATOR: 6:03, we are off the video record.
MS. LEVY: Hang on. We're not going off the record.
We are leaving this transcript open both so the witness can answer this question; in addition, I have a great number of questions still for this witness. Other counsel in this room also have additional questions.
We are going to request -- reserve every right to request additional time with you, Dr. Kessler. So we may be seeing you again.
Anybody else have anything else you'd like to put on the record?
MR. RAFFERTY: Yes. That is that we gave -- Dr. Kessler gave 14 hours per the instructions, was cooperative, answered all of the questions, many of which were irrelevant, harassing, and

Page 807

quite frankly, ethically questionable about his own medical care. And so y'all do whatever you want.
And the other thing is, these will go with the court reporter, and the originals will come back to Dr. Kessler. Any originals that are being copied will come back to Dr. Kessler.
MS. LEVY: Hang on. Everybody in turn.
MS. FREIWALD: I don't care whether I do it or somebody else does it. But by my count, there were 11 of these large spreadsheet files. Somebody can confirm if that's correct or not. Some were marked General.
And please, Dr. Kessler, if you think I'm mischaracterizing it, just say because I'm trying to create a record here.
Some are more general; some were specific to different clients. I saw -- give me one second here.
It looked to me like there were a

Page 808

couple that were Janssen. One was called super poppy; one Purdue; MNK; Actiq; Payments to Parties. And then there was another set that were Market Share, Influencing Doctors, General 1 and 2.
And we're going to ask the court reporter to put an exhibit sticker on each one of those following after whatever our last exhibit number is.
COURT REPORTER: These have already been marked.
MS. FREIWALD: Okay. So the court reporter will keep track of them by number, and she'll make the copies and then get the originals back to Dr. Kessler. That's fine.
COURT REPORTER: Anything else for the record?
MR. RAFFERTY: Nothing from the plaintiffs.
THE WITNESS: Thank you, sir, very much.
Thank you, ma'am.

VIDEO OPERATOR: 6:06 p.m., we are off the video record.

(Off the record at 6:06 p.m.)

C E R T I F I C A T E

I, Lisa V. Feissner, RDR, CRR, CLR, Notary Public, certify that the foregoing is a true and accurate transcript of the deposition of said witness, who was first duly sworn by me on the date and place hereinbefore set forth.

I further certify that I am neither attorney nor counsel for, nor related to or employed by, any of the parties to the action in which this deposition was taken, and further, that I am not a relative or employee of any attorney or counsel employed in this action, nor am I financially interested in this case.

Lisa V. Feissner, RDR, CRR, CLR
Notary Public
Dated: April 30, 2019

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate column on the errata sheet for any change made.

After doing so, please sign the errata sheet and date it.

You are signing it subject to the changes you have noted on the errata sheet, which will be attached to your deposition. You must sign in the space provided. The witness need not be a notary public. Any competent adult may witness your signature.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition may be deemed to be accurate and may be used in court.

WITNESS NAME: DAVID A. KESSLER, M.D.
DEPOSITION DATE: APRIL 26, 2019

ERRATA

PAGE	LINE	CHANGE	REASON

ACKNOWLEDGMENT OF DEPONENT

I hereby acknowledge that I have read the foregoing deposition, pages 420 - 809, dated April 26, 2019, and that the same is a true and correct transcription of the answers given by me to the questions propounded, except for the changes, if any, noted on the attached Errata.

SIGNATURE:
DAVID A. KESSLER, M.D.

DATE:

WITNESSED BY:

DATE:

LAWYER'S NOTES

PAGE	LINE	